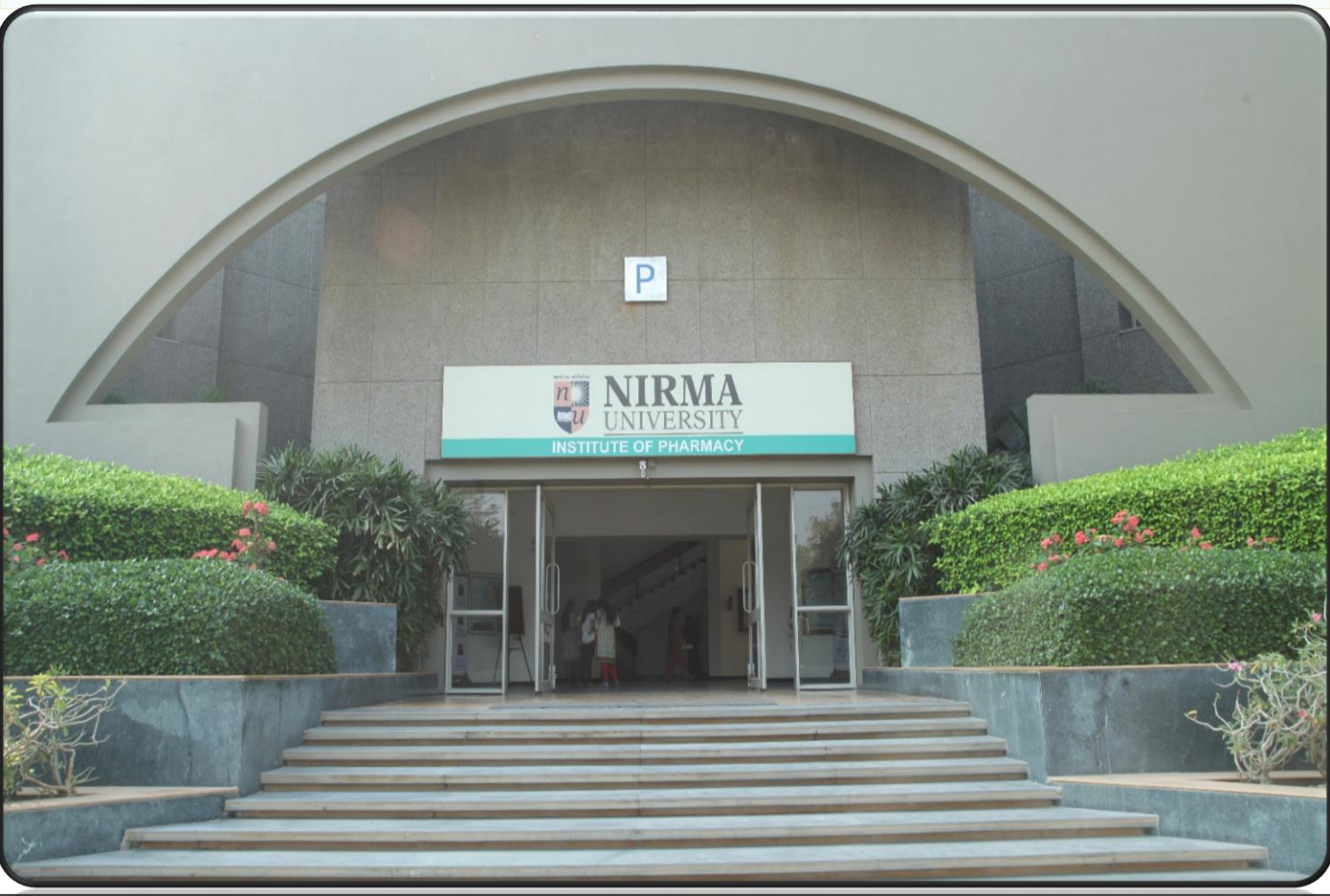
NIRMA UNIVERSITY

INSTITUTE OF PHARMACY

NAAC ACCREDITED 'A+' GRADE

M.Pharm Handbook – II
2022-23



M.Pharm
Hand Book - 2022-23
Volume - II

Section - I

Vision

Striving to excel in pharmaceutical education, research & innovation to develop outstanding professionals catering to the health care needs of the humankind.

Mission

The institute aims to develop employable students, researchers and entrepreneurs by inculcating critical thinking, problem solving ability, ethical values and leadership skills. Institute provides vibrant environment for continuous learning by strengthening industrial collaboration for developing competent professionals.

Programme Educational Objectives (PEOs)

PEO No.	Programme Educational Objectives
PEO1	To acquire effective knowledge of pharmaceutical sciences leading to hold key positions in industry as well as the healthcare sector.
PEO2	To attain practical training and technical expertise in pharmaceutical fields.
PEO3	To inculcate professional and ethical standards with effective interpersonal communication skills.
PEO4	To develop an interdisciplinary pharmaceutical approach towards society benefit, problem solving and lifelong learning.
PEO5	To adapt and implement best practices in the profession by enrichment of knowledge and skills in research and critical thinking.

PROGRAME OUTCOMES

No.	Program Outcomes
PO1	**Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
PO2	**Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines
PO3	**Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
PO4	**Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations
PO5	**Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
PO6	**Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
PO7	**Pharmaceutical Ethics:** Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
PO8	**Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions
PO9	**The Pharmacist and society**: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice
PO10	**Environment and sustainability**: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

PO11	**Life-long learning**: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis
PSO1	**Drugs and diseases**: Understand different classes of drugs, their mechanism of action, dynamics, kinetics, structure activity relationships, pathophysiology and pharmacotherapeutics of various diseases.
PSO2	**Drug development:** Ability to synthesize, develop and/or evaluate various pharmaceuticals and their formulations and cosmeceuticals products
PSO3	**Analytical skills**: Develop skills in qualitative and quantitative analysis of various pharmaceuticals.
PSO4	**Training**: Acquire technical knowledge and hands on training on equipments, instruments and software used in the field of pharmaceutical sciences.

STUDENT'S RIGHTS AND RESPONSIBILITIES

Within the context of the Mission and Vision values of Nirma University, the charter of student rights and responsibilities has been prepared. This charter sets out the fundamental rights of the students with respect to their responsibilities towards their institution. To build the quality and standard of higher education, the entire responsibility heads on teachers, administrative authorities, students, and internal quality assurance cell to improve the eminence of learning along with the National Assessment and Accreditation council (NAAC) playing a synergistic role by providing guidelines and direction.

The charter recognizes that students are central to a dynamic University while, the University recognizes the importance of student rights, responsibilities and opinion and encourages diversity within the student body. The rights and responsibilities enunciated in this document acknowledge the role of students as well as institution to ensure excellence in education.
For this students must be aware of their rights to get quality education and also their duties towards the organization, this in turn encourages Higher Education Institutions (HEIs) to enhance quality. This mutual commitment helps in assuring quality in multiple dimensions.

Institution's responsibilities towards students:

The Institution shall

1. Communicate the vision, mission, programme educational objectives, programme outcomes, rules and regulations of the institution to all students.
2. Offer programmes in-line with pharmacy regulatory authorities.
3. Offer relevant courses with acceptable academic flexibility.
4. Provide relevant learning resources to students.
5. Inform students well in advance about academic calendar, examination and other relevant information.
6. Use feedback from students in the initiation, review and redesign of new programmes.
7. Facilitate for effective teaching-learning processes.
8. Implement a well-conceived plan for observing student development constantly.
9. Ensure that the student evaluation processes are consistent, effective and transparent.
10. Provide flawless information to students about the admission procedures, fee structure, scholarship assistance and student mentoring services.
11. Ensure welfare support services to all students.
12. Encourage values, social responsibilities and moral citizenry in all students.

Student's responsibility of Learning:

The Students shall:

1. Respect the institutional vision, mission and programme educational objectives.
2. Participate and contribute in various institutional activities.
3. Have information of the programmes, admission procedures, and evaluation guidelines of the institution.
4. Follow the rules and regulations of the institution.
5. Undertake systematic and in-depth study of learning materials.
6. Make optimum use of the learning resources and other support services available in the institution.
7. Regularly appear in continuous internal assessment and term-end examinations.
8. Provide constructive and genuine feedback for institute development.
9. Live as worthy alumni of the institution.

CURRICULUM

The institute has introduced an innovative curriculum befitting the needs of the day. It is continuously updated to integrate the rapidly occurring advances in the field of pharmaceutical sciences and drug research. It is vital that institutes and teachers recognize their responsibility in preparing not only responsible members of the healthcare team but also valuable members of the society, who must have top quality scientific and professional skills, and an unquestionable sense of ethics.

The contents of course have been carefully considered to ensure that they are relevant and up-to-date and special consideration has been given to the applications of knowledge, communication, language and patient care skills, healthcare system organizations, the development of professional identity, critical thinking and lifelong learning. It is mandatory for all universities to follow the curriculum of Pharmacy Council of India (PCI) and institutes are following the syllabus of PCI with modification in learning process.

Special features

The Institute of Pharmacy is a constituent unit of Nirma University. The M.Pharm programme is approved by Pharmacy Council of India (PCI) with an intake of 54 seats (additional 15 sears of Pharmaceutical Chemistry are in abeyance) . The special features of our programmes are:

- A 125-acre sprawling campus in picturesque surroundings, which provides a refreshing environment, stimulating intellectual alertness and creativity
- Innovative dynamic curriculum befitting the current needs of industry and adopting OBE
- Teaching of value added, enrichment and add-on courses, university electives, audit courses, MOOC courses and self-study course in curriculum, social extension and NSS related activities, and inputs and seamless university examination system for evaluation and grading
- Classroom plus ICT based interactive teaching learning using modern tools, web resources and wi- fi facility
- Supplementary learning activities with practical training in industries during summer
- State- of –the- Art laboratories for PG Studies and Research
- Collaboration with research Institutions and industries like: Plovdiv University, Bulgaria, B. V. Patel, PERD Centre, Ahmedabad, Cadila Pharmaceutical Research

Centre & Intas Pharmaceuticals Ltd., Piramal Pharmaceutical Development Services (P) Ltd., Ahmedabad, CII, Ayurlab Herbal Pvt, Ltd. Vadodara & Beiersdorf (Nivea) Germany, Brillare Sciences, Ahmedabad, Finecure, Ahmedabad, CPC, Ahmedabad and Evonik, India.

- Excellent hostel for PG & PhD students on the campus
- Highly Qualified Faculty having PhD and research experience with various awards, patents & publications in reputed journals
- M.Pharm students and research guides have received national recognition for Best Thesis in PharmaInnova Award Competitions supported by DST and Troikaa Pharmaceuticals Ltd.
- Advisory Committee comprising eminent personalities of Academia and Industries
- Stipend to the Meritorious GPAT and Non-GPAT Students as per Nirma University norms
- Regular visits to the industries, CROs and R&D centers and a strong industry-academy interaction and regular visiting faculty from industries
- Constant mentoring to the students by the faculty on a one to one basis on career guidance for personal development, identification of aptitudes and motivation in right direction
- Grooming and training of students with development of communication skills and extensive guidance for GPAT, TOEFL, GRE etc.
- Use of plagiarism policy for thesis checking and report is attached with thesis
- Dedicated Industry Institute Interaction cell, for training and grooming of students for effective transition from campus to company

The approach to learning

The institute makes use of an appropriate mix of pedagogical tools to train students to handle professional responsibilities. These include lectures by an appropriate mix of in-house and visiting faculty, expert lectures, discussions, seminars, project assignments, and visits to industries. The laboratory practical related to the theory course are included in the syllabus to acquaint the students with practical knowledge. Continuous Evaluation and counselling are important parts of the academic programme.

- Rigorous coaching with Continuous Evaluation
- Credit Based Semester System with weightage of different components of study

- Learning through Classroom Teaching, Practical Work, Industry Visits and Project Work
- Academic Rigor and Innovative Pedagogical Tools
- Faculty guidance and mentoring system with faculty as counsellors to students
- Continuous enhancement of communication skills
- Continuous Up-gradation of State -of –the- Art knowledge and skills
- Active participation of students in creative co-curricular Activities.
- Portion of syllabus is covered by industrial expert in each course
- Quality policy for various aspects like curriculum design and development, teaching-learning and evaluation, teacher quality, infrastructure and learning resources and student support, research, consultancy and extension activities and monitoring and review of quality.
- IT Policy for using the IT resources, whether personally or of University owned, which access, transmit or store various types of related information
- Idea lab for carrying research on new idea by the students

ACADEMIC INFRASTRUCTURE/FACILITIES

The Campus

The Institute of Pharmacy is situated on the sprawling 115 acre green campus of Nirma University. It has all the modern facilities like sophisticated Instruments, state of the art labs, excellent computing & IT infrastructure including latest software, rich library, canteen, playgrounds, indoor games and gymnasium. The campus provides an ambience that motivates the students to grow. The Institute building has modern amenities, with enough space and replenished with modernity and grandeur. The post graduate laboratories are independently developed for M.Pharm and PhD students. In addition the campus has sports facilities and the overall ambience is distinguishable by its serenity, which is conducive for intellectual pursuits.

Sophisticated Instruments

The Institute has two separate sophisticated instrument laboratories equipped with modern instruments. Modern instruments are the most essential part of all research activities which facilitate interdisciplinary research. The instruments available at the institute are:

- Fourier Transform Infrared Spectrometer
- Fluorescence Spectrometer
- Supercritical Fluid Chromatograph / Extractor
- UV-Visible Spectrophotometer
- UV-Visible/NIR Spectrophotometer
- High Performance Liquid Chromatographs (with binary & quarternary pumps, UV, PDA & RI detectors)
- Gas Chromatograph
- High Performance Thin Layer Chromatograph
- Differential Scanning Calorimeter

Besides these, the Institute also has other high end instruments like high pressure homogenizer, particle size analyzer, zeta potential analyser, lyophiliser, high speed homogeniser, stereotaxic apparatus, microdialysis system, hematoanalyser, semi-automated biochemical analyzer, ELISA, PCR and gel documentation system.

Machine Room

The machine room is equipped with Rotary Tablet Machine, Fluidized Bed Drier cum Coater, Digital TensioMeter, Texture Analyzer, Mini Spray Dryer, Freeze dryer, Automated Dissolution Apparatus, projection microscope, vaccum drier, ultrasonificator etc. The laboratory provides facilities to carry out extensive research and consultancy for pharmaceutical industries.

Drug Discovery Lab

The Institute has a separate Drug Discovery Laboratory equipped with necessary computational facilities. It possesses seven workstations (computers) with latest configurations. It also possesses molecular modeling software. The students are trained on the software for docking, pharmacophore modelling and QSAR studies etc.

Animal House

The Institute has state-of-the-art animal house facility registered by the CPCSEA, Government of India. It provides pre-clinical testing in conformity with national and international regulatory guidelines (Schedule Y and OECD). The animal house facilitates the availability of healthy and homogeneous animals for research. Pre-clinical studies related to efficacy, safety and toxicological evaluation of a new chemical entity, formulation and nutraceuticals can be carried out. An incinerator is also available at the animal house for ethical disposal of the sacrificed animals.

Nirma Herbal Wealth

The department houses a well-developed medicinal plant garden “Nirma Herbal Wealth” covering a total area of 3356.5 sq. meters with more than 153 varieties of species and more than 500 plants extending the scope to carry out research on medicinal plants. The garden houses a variety of medicinally important herbs, shrubs and trees spread in a well-defined area. The plants grown are useful to conduct the practical sessions of pharmacognosy and herbal drug technology. This well-developed medicinal plant garden provides a strong impetus for herbal drug research and to impart training to the graduate students. It supplies crude raw material and fresh plant specimens essential to carry out herbal drug and natural product-related research by the graduate, postgraduate and doctoral students of Institute of Pharmacy. Students of the Institute of Pharmacy use the botanical garden to collect the herbs for their routine practical work as well as for their research work during their project. Students collect the plant parts based on their project need to prepare the extract and isolate the important phytoconstituents with therapeutic importance. The collection of plants is also

useful to prepare herbarium specimens by undergraduate students. Some of the trees available at the garden include *Terminalia arjuna* (Arjuna), *Saraca asoca* (Ashoka), *Moringa oleifera* (Drumstick), *Azadirachta indica* (Neem) and *Ficus carica* (Anjeer). Some of the important plant species are *Datura metel, Commiphora mukul, Gmelina arborea, Cymbopogon citratus, Vetiveria zizanoids, and Plumbago zeylanica.*

Class Rooms

The classrooms are spacious, ventilated and equipped with multimedia and audiovisual equipment to facilitate effective learning. The classrooms are designed to provide maximum interaction between the faculty and students.

I.T Infrastructure

The computer facility at the Institute of Pharmacy includes two laboratories equipped with 48 computers for the students. The computers are equipped with fiber optic cables and 512 Mbps leased line internet connectivity. The campus is also equipped with Wi-Fi network facility. An integrated MIS system for the student's attendance and academic record is available.

DEPARTMENTS & FACULTIES

Department of Pharmaceutical Chemistry

The Department of Pharmaceutical Chemistry is an integral part of pharmacy education involving several aspects of new drug discovery and development in collaboration with other disciplines of pharmacy. As a part of undergraduate teaching and learning, various subjects included are Pharmaceutical Inorganic Chemistry, Biochemistry, Pharmaceutical Organic Chemistry, Medicinal Chemistry, and Computer Aided Drug Design. Extensive use of modern audio-visual teaching aids and molecular models make the lessons interesting and student-centric. The department has collaborations with various research organizations, industries and basic science departments where students can participate in interdisciplinary research projects relevant to core areas. The research projects help students to get deep insights in the research area and help to develop expertise. The students are also encouraged for various other activities like personality, communication and soft skills development; scientific writing; workshops for improvement in presentation and documentation skills, etc. Alumni members of the department are placed at various places like R&D, CRO and academic institutions, etc. as well as pursuing their doctoral studies in reputed universities across the globe. The department is also involved in Doctoral research and students received many research scholarships for PhD programmes viz. DST-Inspire, ICMR, etc. and are also supported by Nirma University schemes.

Dr Hardik Bhatt

Dr Hardik Bhatt is working as Associate Professor and Head in Dept of Pharmaceutical Chemistry and has more than 18 years of teaching & research experiences. He is also looking after the Centre for Advanced Instrumentation (CAI) facility at Nirma University. He completed his PhD from Nirma University in 2009. Dr Bhatt is a recipient of Gold Medal for standing First in MPharm in Pharmaceutical Chemistry at Gujarat University in 2004. His areas of research interest are drug design, molecular modelling, synthesis of NCEs and their evaluation as potent therapeutic agents in areas of Cancer, HIV, Tuberculosis, etc. He is also working in the area of analytical method development. He has published more than 45 research and review articles in reputed international and national journals and authored 5 books including three editions of “Practicals in Organic and Medicinal Chemistry” and first edition of “Practicals in Pharmaceutical Analysis I” and a book chapter in Academic Press, Elsevier Publication. Dr Bhatt has working experience in various major and minor research projects sponsored by GSBTM, GUJCOST and Nirma University. He had presented research

papers at various international and national conferences including 245 ACS Annual Meeting and Exposition, Louisiana, USA; 2009 AAPS Annual Meeting and Exposition, Los Angeles, USA; ISCB Conferences; National Conference at IIT-G; Indian Pharmaceutical Congress (IPC) and at state level paper presentation competitions sponsored by GUJCOST. Dr Bhatt has received various travel grants from DST, ICMR, CSIR, etc. Research papers presented or co-authored by him won several prizes at various conferences. Overall he has more than 100 presentations to his credit. He has reviewed international research grants as well as many articles. Dr Bhatt is recognized PG and PhD guide of Nirma University. He has been actively involved in various capacities in organizing national and international conferences/workshops. Dr Bhatt is a member of Royal Society of Chemistry (MRSC), American Chemical Society, Indian Pharmaceutical Association, Indian Society for Chemists and Biologists, Association for Pharmacy Teachers of India & Indian Society for Technical Education.

Dr Jignasa Savjani

Dr Jignasa Savjani is currently working as an Assistant Professor at the Institute of Pharmacy, Nirma University, Ahmedabad, India. She has 18 years of academic and research experience. She has been actively involved in research since 2007. She completed her PhD from Nirma University in the year 2011. She is the prestigious American Chemical Society grant recipient to attend and present research work during the Pittcon 2018 conference in Orlando, USA. She has two Indian patents to her credits. In addition, she delivered various expert lectures on topics related to Pharmaceutical Chemistry. Her research studies involve national and international collaborations. She has received financial assistance from CSIR and DST to present research work during international conferences in the USA. She published research and review articles in internationally reputed journals. She currently works in the areas involving the design and development of small heterocyclic molecules; co-crystallization approaches to improve the solubility of poorly soluble drugs.

Dr Vivek Vyas

Dr Vivek Vyas is working as Assistant Professor in Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad. He has more than 14.5 years of teaching and research experience. He is a recognized PhD guide at Nirma University. He teaches various courses like Biochemistry, Medicinal Chemistry, Organic Chemistry, Computer-Aided Drug Design, etc at UG and PG level. He has published more than 50 research and review articles in National and International journals of repute. He is a reviewer of international and national journals like JMC, ACS Omega, ACS infectious Diseases, EJMC,

RSC, ACS, BMCL, CADD, SAQE, MCR, AJC, IJC B etc. He has completed a minor research project granted from GUJCOST, Gandhinagar, Gujarat. He has presented research papers at various national and international conferences and seminars. Overall he has 27 presentations to his credit. His areas of research are Computer Aided Drug Design (CADD), Molecular Modeling, QSAR, Pharmacophore Mapping and Synthesis of novel heterocyclic ring systems as Anticancer and Antimalarial agents. Dr Vyas is a member of American Chemical Society, Indian Pharmaceutical Association, Indian Society for Chemists and Biologists, Association for Pharmacy Teachers of India & Indian Society for Technical Education.

Dr Bhumika Patel

Dr Bhumika D Patel is working as an Assistant Professor in the Department of Pharmaceutical Chemistry. She has 13.5 years of teaching experience. She is a recognized PhD guide at Nirma University. She teaches various courses like Medicinal Chemistry, Organic Chemistry, Computer-Aided Drug Design, Biochemistry, etc at UG and PG level. At present, she is a coordinator of UG Research Council and Students' projects at the Institute. Her area of research includes the rational design and synthesis of different heterocyclic compounds under various therapeutic classes like diabetes, cancer, HIV, etc. She has a sound knowledge of drug designing software like Sybyl, Discovery Studio, Gold, Schrodinger, etc. She has 17 international publications in reputed journals and 24 presentations in her credit. She presented a research poster at the 257th ACS Annual Meeting and Exposition held at Orlando, Florida, USA during March-April 2019 for which she received full travel assistance from SERB, Department of Science and Technology, Government of India. Currently, she is working on a Minor research project on design and synthesis of novel PARP1 inhibitors funded by Nirma University. She received Best Assistant Professor Award 2018-19 for the Overall Performance in Teaching, Co-Curricular Activities and Research from Nirma University. She completed one minor research project of GUJCOST and two MRPs of Nirma University. She is a recognized PhD guide at Nirma University and currently she is guiding 2 PhD candidates. She has guided 17 PG students as a research guide/co-guide. She is a life member of professional bodies like APTI, IPA, ISCB (Indian Society of Chemists and Biologists), RSSDI (Research Society for the Study of Diabetes in India) ISTE (Indian Society for Technical Education), etc.

Dr. Udit Chaube

Dr. Udit Chaube is working as an Assistant Professor in the Department of Pharmaceutical Chemistry, Institute of Pharmacy, Nirma University, Ahmedabad. He has 7.5 years of research and teaching experience. He has completed his full time PhD from the Institute ofPharmacy,

Nirma University, with DST-INSPIRE Fellowship received from the Department of Science & Technology, Government of India. Dr Udit Chaube is a recipient of Gold Medal for standing First in M.Pharm in Drug Discovery at Nirma University in 2014. He has published 7 research articles in International Journals of repute. Prior to joining the Institute of Pharmacy, Nirma University, Dr. Udit Chaube worked with the National Innovation Foundation-India, Autonomous Body of Department of Science & Technology, Government of India. He has presented research papers at various National and International Conferences and Seminars. Overall, he has more than 6 presentations to his credit. He has expertise in Synthetic Chemistry, Computational Chemistry, Cell-Culture & In-Vivo Biological Evaluation.

Department of Pharmaceutics

Pharmaceutics, a multidisciplinary science, is associated with the development, production, and characterization of dosage forms/drug delivery as well as the disposition and action of drugs in the body. The Department of Pharmaceutics offers courses at undergraduate, postgraduate and doctoral levels. Students are trained towards the basic concepts to the latest developments in pharmaceutics and pharmaceutical technology as per the needs of society. The department works towards promoting a strong multidisciplinary, team-based approach to drug delivery, embracing a variety of activities in the broad area of drug formulation and delivery. The faculty members and students at the department contribute to research through funded projects, industrial projects, consultancy, etc. to formulate novel formulations.

Prof Tejal Mehta

Dr Tejal is presently working as Dean, I/c Director, Institute of Pharmacy , Nirma University, Ahmedabad. She has done her PhD from Sardar Patel University, Vallabh Vidyanagar and BPharm and MPharm in "Pharmaceutics & Pharmaceutical Technology" from Gujarat University, Ahmedabad. She has 21 years of teaching and 16 years of research experience. Her area of research is Dissolution enhancement of sparingly soluble drugs and formulation development of conventional and novel drug delivery systems using concepts of QbD-DoE. She has published more than 70 research papers in journals of national and international repute. She has also presented several papers in national and international conferences. She has authored a chapter in a multi-authored book on Novel Drug Delivery Systems. She has received Best Paper Award 2004 from Association of Pharmaceutical Teacher's of India for publishing paper in Indian Journal of Pharmaceutical Education. She also received the R V Patel Best MPharm thesis award in the Guide category. She has also authored the book

“Practical Manual of Pharmaceutical Engineering” and “Practical Manual of Pharmaceutical Dosage Forms''. She has filed 3 patents related to her research. She has successfully completed GUJCOST sponsored minor research projects related to formulation development. She has delivered lectures in various staff development programs. She is a recognised PG and PhD Guide of Nirma University. She is a reviewer of national and international journals in the research area of Pharmaceutics and Drug Delivery. She is a life member of APTI, IPGA, and Society of Pharmacovigilance of India.

Dr Mayur Patel

Dr Mayur Patel has 15 years of teaching experience. He has more than 40 International and National Publications with a total impact factor of more than 150, total citations more than 1500 and ‘h’ index of 18. He is a recipient of a major research project from Nirma University worth Rs. 28,92,400/-. He is also the recipient of a minor research project worth Rs. 4,00,000/- from Gujarat Council on Science and Technology (GUJCOST). He is reviewer for many high impact factors journals of publishers like PLOS One, Elsevier, Informa Healthcare Ltd., American Chemical Society (ACS), to name a few. Dr. Patel has received the Prestigious "Young Pharmacy Teacher of the Year Award - 2019" from "Association of Pharmaceutical Teachers of India (APTI)”. He received second prize in EUDRAGIT® Award 2016 for publishing highly innovative papers at National Level. He has also written 02 book chapters in books published by International Publication House namely Encyclopedia of Pharmaceutical Science and Technology, Informa Healthcare Inc. UK and Lipid Nanocarriers for Drug Targeting, Elsevier B.V. He was felicitated Six times for “Outstanding Performance” for the year 2011, 2012, 2013, 2014, 2016, 2018, 2019 and 2020 during foundation day at Nirma University. He is a recognized PG and Ph.D. guide at Nirma University.

Dr Shital Butani

Dr Shital Butani has more than 20 years of research and teaching experience. She has received a Major project entitled "Exploring non-equilibrium atmospheric plasma for effective sterilization including biological safety aspects” from the Board of Research in Nuclear Sciences (BRNS), Department of Atomic Energy, Government of India.", another project for the development of an oral formulation for a natural product as well as nasal and oral spray for an Indian Industry; a minor project from Gujcost entitled "Development of self-emulsifying drug delivery system of the poorly water soluble antihypertensive drug", a travel grant from DST to attend the conference in Lisbon, Portugal. She has guided five PhD students (including students having WOS A and CSIR fellowship). Dr Butani has received "Project

Excellent" award during her tenure at Zydus Cadila Healthcare Ltd., Ahmedabad. She also received a best paper award from IDMA in January 2015 for one of her publications in the Pharmaceutics category. She was a volleyball player in the junior level team of Gujarat and played national competition at Tripura. She has published many papers in reputed national and international journals. She is a recognized PhD guide and a member in ISTE, APTI, IPGA etc bodies.

Dr Jigar Shah

Dr Jigar Shah has 17 years of teaching and 8 months of industrial experience. He is author and co-author of around 70 research and review papers presented at International conferences including conferences at Washington DC, USA (2011), and Vancouver, Canada (2016), with international travel grants (Total Rs.4,50,000/-) received from Govt. Agencies like SERB, DST, CICS and ICMR respectively. He received the "Best Presentation Award" at an International conference in Canada. He has published 54 research and review papers in high impact factor Journals (total impact factor more than 200, total citations more than 801 and h-index is 17). He has written 04 book chapters and 01 book, with highly reputed publishers like CRC Press, Taylor and Francis, John Wiley & sons, etc. He had successfully completed the research project sponsored by GUJCOST (worth Rs. 7,00,000), received various research grants from Nirma University (total Rs. 5,00,000) and international grants as coinvesitgator (total Rs.21,00,000) from agencies of King of Saudi Arabia. He is a recognized PhD, PG Guide at Nirma University. He has submitted 03 patents to Indian Patent Office for publications. His area of interest is Novel drug delivery systems. He is an academic editor, toic editor and reviewer of the various reputed International Journals of Elsevier, Springer, Bentham Science, Frontiers, Informa Healthcare and Wiley etc. He is invited for research grant review by QNRF, and Ajman University, UAE. He is a recipient of GOLD MEDAL in M. Pharm. programme in the year 2004 and 2005. He has received many awards and prizes for best research papers in the paper presentation category. He is felicitated a number of times for "Outstanding Performance" as a faculty and researcher for the years 2012, 2014, 2017, 2020, 2021 during foundation day at Nirma University. He is a member of various international and national pharmacy societies like AAPS, CRS, WASET, IPA, APTI, ISTE, IPGA, SPER, and IHPA.

Dr Dhaivat Parikh

Dr Dhaivat Parikh has more than 16 years of teaching and research experience. He is a recipient of Best Assistant Professor of Institute for Innovation in Teaching Methodologies for the year 2015 by Nirma University. He was also felicitated in 2020 for significant contributions

for Alumni Relations. He is actively involved in Consultancy and Testing at the Department. His major area of interest is Novel Drug Delivery Systems (specifically to Gastro-Retentive Drug Delivery Systems, Formulations for Oral Cavity, Medicated Chewing Gum, Cosmeceuticals, etc). Currently, his major role at the institute is BPharm Admission Coordinator, Vice President of IPNUAA (Alumni Association), Faculty Coordinator for Library, etc. He has Eight International publications to his credit including two articles in Expert Opinion on Drug Delivery (having a high impact factor above 4). He has also been awarded "Outstanding Faculty Award" for his significant contribution to the development of the University website. He has presented his Research work by an Oral presentation at International conference PharmaTech-2012 held at Kuala Lumpur, Malaysia; as well as presented a research poster at International Conference - APSGB's PharmSci 2014 held at University of Hertfordshire, UK. He is a life member of many Professional bodies like APTI, IPA, ISTE, ISCB, CRS-IC, IPGA, IHPA, APA, SDPS, ABAP, APP, IACP etc. He is rendering his professional services to many leading Universities of Gujarat.

Dr Mohit Shah

Dr Mohit Shah has around 12 years of research and industrial experience. He has completed MPharm and PhD from Institute of Pharmacy, Nirma University. He is actively involved in teaching various subjects related to pharmaceutics at UG and PG level and research in the field of solubility enhancement. He is proficient at analyzing and interpreting patent literature and technical data, preparing a patent landscape and performing Non-infringement and FTO Analysis. He has 3 granted patents and 4 International Publications to his credit. He has been an author and co-author of 5 papers/posters presented at state and national level seminars and conferences. He is a recipient of the Best Student award for M Pharm program. He has attended 18 International and National level conferences and workshops. His area of interest is Novel Drug Delivery Systems.

Department of Pharmacology

Pharmacology is a unique and dynamic branch of pharmacy, since it involves the understanding of how a drug deals with the human body and how the human body responds to the drug. The department offers undergraduate courses like Anatomy and Physiology, Pharmacology, Pathophysiology and Clinical Pharmacy and Pharmacotherapeutics. The post-graduate programme in Pharmacology focuses on research-oriented courses like Cellular and Molecular Pharmacology, Clinical Research and Pharmacovigilance, etc. The department has collaborations with research institutes, pharmaceutical industries, hospitals and other basic

science departments where students can participate in interdisciplinary research projects that are relevant to pharmacology. The research projects facilitate a critical examination of pharmacological approaches and analyses/techniques used in *in-vitro/in-vivo* research and produce a comprehensive dissertation and present their findings. The students are motivated for overall development, including- personality development, scientific writing, data interpretation, presentation, documentation, good laboratory practices, communication, and soft skills. Alumni members of the department are placed in preclinical research and development, clinical research, data management, pharmacovigilance, medical writing at various industries, CRO's and reputed academic institutions. The department has received several consultancy and collaborative research projects from various government agencies and pharmaceutical industries. Research scholarships for PhD programmes are awarded on a competitive basis and are supported by University schemes.

Prof Jigna Shah

Dr Jigna Shah is currently working as a Professor and Head at Department of Pharmacology at Institute of Pharmacy, Nirma University, Ahmedabad. She is actively involved in oncology and neurodegenerative disorders research. Her area of research interest is oncology, neuropharmacology, metabolic disorders, Clinical research, and Pharmacovigilance. Currently, she is working on the externally funded research project from GSBTM, and industry as well as Nirma University funded major research project in the area of oncology. She has successfully completed four externally funded research projects from GSBTM, AICTE and GUJCOST. She has also completed a few consultancy assignments in the area of toxicity studies, oncology neuropharmacology, gastroenterology, and wound healing also. She has guided several postgraduate students and presently guiding 7 PhD students. She has published more than 48 research papers in reputed journals. She was awarded Gold medal for securing highest marks in the final year BPharm in Pharmacology subject at L. M. College of Pharmacy, Ahmedabad. She has also won awards for the best paper presentation at various national and international conferences. She is a life member of professional organizations like Association of Pharmacy Teachers of India, Indian Pharmaceutical Association, Indian Pharmacological Society, Indian Society for Technical Education and Indian Society of Pharmacovigilance.

Dr Shital Panchal

Dr Shital Panchal is working as an Associate Professor in the Department of Pharmacology. She has more than 19 years of teaching and research experience. She has published more

than 65 articles in reputed journals and 2 books. Current areas of research are nutraceuticals, clinical trials, pre-clinical studies, kinetic studies, toxicity studies, metabolic, GI and neurological disorders and epidemiology. She has received major and minor research projects from Government funding agencies and Industries like ICMR, AP Organics Ltd(India), ProbioticSmart LLP (USA), GUJCOST,and Nirma University as a principal investigator. She has worked as consultant for pharmaceutical and nutraceutical companies in India and USA, like Intas biopharmaceuticals, Troikaa Pharmaceuticals, Pharmanza Herbal Pvt Ltd, ProbioticSmart LLP (USA), etc. She has presented research work in many national and international conferences and chaired scientific sessions, delivered lectures in conferences. She is a member of professional bodies like Indian Pharmacological society, APTI IPA, ISTE. She is a recognised PG and PhD guide at Nirma University.

Dr Snehal Patel

Dr. Snehal S Patel, has 20.5 years of teaching, industrial and research experience. She has carried out many consultancy projects for pharmaceutical companies, institutes, hospitals, and allied industries. She has completed major research projects from SERB under the Fast Track Scheme for Young Scientists and is currently working on an ICMR-DHR sponsored major research project. She has also completed two minor research projects from GUJCOST and Research Society for Study for Diabetes In India as investigator. She has also worked as a co-investigator in two major research projects from the Ministry of AYUSH and from the Ministry of Atomic energy and in five interdisciplinary minor research projects supported by GUJCOST. She has published 93 research and review articles, 2 book chapters, and 2 books in international and national journals and publication houses of repute with total impact factor more than 175, 'h' index 20, and 1600 citations. She has worked as a Research Scientist at Sun Pharmaceutical Advanced Research Centre and as a Senior Research Fellow at Center for Advanced Cardiovascular and Diabetic Research at LMCP under AICTE. She has presented more than 30 papers at national and international conferences. She is a life member of several professional bodies including RSSDI, APTI, IPS, ISTE. She is a recognized PG and PhD guide at Nirma University. Her areas of interest are metabolic disorders and its complications, immunology and cancer.

Dr Bhagwati Saxena

Dr. Bhagawati Saxena is working as an Assistant Professor in the Department of Pharmacology, Institute of Pharmacy, Nirma University. She has around 13 years of research and teaching experience. She has completed M.S. (Pharm.) from National Institute of Pharmaceutical Education and Research (NIPER), S.A.S, Nagar and Ph.D. from Indian Institute of Technology (Banaras Hindu University) (IIT-BHU). She has received UGC-Junior Research Fellowship and CSIR-Senior Research Fellowship for carrying out her PhD research work. She has worked in the National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad for nearly two years as an Assistant Professor. Her Research Interest include Investigation of new therapeutic targets for the treatment of various neurological diseases (Traumatic brain injury, Alzheimer's disease, Parkinson's disease, Stress and Stress related disorder), Phytopharmacological screening, Toxicity and Pharmacokinetic studies. She has 17 International and National Publications in reputed Journals, 4 Book Chapters and 3 Patents to her credits. She has attended various seminars, workshops, presented papers and delivered Invited lectures at the various national and international level conferences including the one at AAPS Annual Meeting and Exposition, New Orleans, USA and Singapore Pharmacy Congress at Singapore for which she has received full travel grant from the Department of Biotechnology (DBT), Government of India and INSA-CICS (Indian National Science Academy in association with Centre for International Co-operation in Science) respectively. She is reviewer for many journals like NeuroToxicology, Brain Research Bulletin, Neurotoxicity Research, Molecular Biology Reports etc. She has completed one minor research project sponsored by Nirma University. She is recipient of 7th Venus International Women Awards – VIWA 2022, InSc Young Researcher Award 2020 and Best Poster award at Recent Advances in Pharmaceutical Sciences (RAPS) 2010 at IIT, BHU. She is a recognized PG and PhD guide at Nirma University. She has guided 14 postgraduate students as Research Guide/Co-Guide. She is a life-time member of professional bodies like the Indian Academy of Neuroscience (IAN), Association of Pharmaceutical Teachers of India (APTI) and Indian Pharmacological Society (IPS).

Dr Richa Gupta

Dr. Richa Gupta is working as Assistant Professor in the Department of Pharmacology. She is having the more than 10 years of research and teaching experience. She has completed her PhD at most reputed labs of India CSIR- Indian institute of toxicology research, Lucknow. She was the gold medallists throughout B. Pharm and M. Pharm. She received the CSIR- Junior and senior research fellowship for carrying out her PhD work. Apart from that she is also

Recipient of ICMR- Research associate fellowship and DST inspire fellowship. Her research area includes neuropharmacology and neurotoxicology on identifying the molecular and cellular mechanisms of drug induced movement and cognitive dysfunctions. She Published more than 17 international papers, book chapters in reputed journals. Her work has been recognized at various international platforms like Japan, Singapore, Vietnam, USA, Italy, Vancouver, Nice, Paris and many more. She is also the holder of international travel grants like IBRO, ISN, MDS and many more. She also received travel grants from DST, DBT, ICMR and CSIR for presenting her work at international platforms. She is peer reviewer of many journals with high impact factor including the Nature, "Scientific Reports", Elsevier, Springer, toxicology international and many more. She is the life member of IBRO, MDS, IPS, IAN and many more.

Department of Pharmaceutical Analysis

The Department of Pharmaceutical Analysis deals with the analysis of the raw materials as well as finished pharmaceutical formulations which are very important for the evaluation of quality, safety, and efficacy of pharmaceutical products. At the undergraduate level, the department is involved in imparting theoretical as well as practical knowledge of the subject that a student needs to acquire the current scenario of quality control and quality assurance of pharmaceutical substances as per the need of the Pharmaceutical Industry and regulatory requirement. The subject includes an introduction to pharmacopoeias (IP, BP, USP, and others) and different analytical methodology used in pharmacopoeias for the analysis of drug substances and Drug Products. The department provides an exhaustive postgraduate programme focused on research and coursework relating to most recent advances in pharmaceutical and biomedical analysis, quality assurance as well as regulatory affairs. The students are motivated for overall development, including personality development, scientific writing, data interpretation, presentation, documentation, good laboratory practices, communication, and soft skills. Full time PhD students of the department got research fellowship from CSIR, ICMR, DST, DST-INSPIRE and Nirma University. Faculty members of the department are actively involved in interdisciplinary research work and collaborate with scientists of various reputed research organisations, academic institutes, and industry.

Prof Priti Mehta

Dr Priti Mehta, Chair Professor of Pharmaceutical Analysis at Institute of Pharmacy, Nirma University, has more than 22 years of teaching, research and industrial experience. She started a postgraduate programme of Pharmaceutical Regulatory Affairs at Institute. Her area of expertise encompasses stability studies of drugs, Impurity profiling, elucidation of degradation pathways of drugs, isolation and characterisation of active moiety from plant and marine seaweeds, bioequivalence and bioavailability studies, development of long acting formulations, effects of radiation exposure on medicines, development of radioprotectors, etc. She is a pioneer in getting interdisciplinary research grants at Nirma University. Dr Mehta worked on many research projects from government funding agencies, like AYUSH, ISRO, BRNS, GUJCOST etc. She is mentor of Women Scientist under WOS-A scheme of DST. Under her guidance many students got research fellowships from CSIR, DST-INSPIRE, ICMR etc. Dr Mehta has published a number of research papers and review articles in peer reviewed scientific journals. She has presented research papers in International conferences in the USA. Dr Mehta has delivered guest lectures at various Institutions during seminars, workshops and staff development programmes. She has rendered professional services to leading universities in various capacities. One patent was granted for her research work and she has guided 12 PhD students for pharmaceutical Research. Her research students won scientific poster awards at national forums. She is a recipient of the prestigious M L Khurana award for the best research paper in Pharmaceutical Analysis. She is also recipient of P D Sethi award and R V Patel Best thesis award in guide category. She was conferred prestigious APTI woman of the year 2018 award by Association of Pharmaceutical Teachers of India for her scientific and academic contribution.

Dr Charmy Kothari

Dr Charmy S. Kothari is working as Associate Professor in the Department of Pharmaceutical Analysis and has more than 18 years of teaching and research experience. Her research areas of interest are analytical and bio analytical method development and validation, impurity profiling and stability studies as well as Isolation, identification and characterization of marker compounds from plants and formulations and pharmacokinetic study. Her research area also includes regulatory guidelines, registration procedures, evaluation and approval procedures of various regulatory agencies worldwide as well as Pharmacovigilance systems. She has more than 50 research and review papers published in reputed Indian and International journals. One of her papers has been published in the prestigious Elsevier journal Trends in Analytical Chemistry (IF=14.908). She is a reviewer of several national & international journals in her

research area of interest. She has presented a paper as well as various posters at international, national and state level conferences and received several awards for best oral and poster presentation. She is twice the recipient of Dr P. D. Sethi memorial annual national award for research paper certificate for the year 2007 and 2017. She is actively involved in various capacities in organizing National and International Conferences/Workshops. She has also received financial assistance from GUJCOST for organizing workshops and National seminars. She is a life member of various organizations like RAPS, ACS, APTI, IPA & ISTE. She is a recognized Post Graduate and Ph. D. Guide at Institute of Pharmacy, Nirma University. Under her guidance, three PhD students were awarded an ICMR-SRF research grant; while one PhD. student received prestigious CM fellowship-SHODH from Government of Gujarat for research work. She received research grants from government funding agencies like GUJCOST, DST, ICMR and Nirma University. She also received DST-SERB International Travel Grant to attend the International Conference AOAC at Toronto, Canada.

Dr Nrupesh Patel

Dr Nrupesh has been working as an Assistant Professor at Nirma University since January 2008. He has completed two minor research projects sponsored by Nirma University. He has 16 years of teaching experience. He has presented various posters and papers at international and national level conferences and competitions like GUJCOST-2004, ISAS-2005, NCIP, RBF-ZRC conference, NIPICON, ICONICA-2020 etc. He has published 13 papers in reputed international and national journals. His areas of research are spectroscopic and chromatographic analytical method development and validation of analytical methods. He is a life member of professional bodies like ISTE, APTI & IPA.

Department of Pharmacognosy

The Department of Pharmacognosy is engaged in imparting basic and advanced aspects of different natural sources as pharmaceutical raw materials, traditional medicines, phytochemical screening, and scope of Indian medicinal plants in the allied sciences like food, nutraceuticals, and cosmetics. The department deals with theoretical as well as practical knowledge of undergraduate courses related to pharmacognosy, phytochemistry, analytical pharmacognosy, the chemistry of natural products, herbal drug technology, and nutraceuticals. The department is offering consultancy services to the herbal drug industries, various research institutes, and cosmetic companies and successfully completed many consultancy projects. Several students are pursuing their PhD under the guidance of the able

faculties in the department with research fellowships under the Government scheme of DBT, INSPIRE-DST and Women Scientist WOS-A.

Dr Niyati Acharya

Dr. Niyati has 19 years of experience in teaching and natural product research, published 38 research papers, 4 book chapters, 1 patent and presented more than 80 posters. She has completed research projects from DBT and GUJCOST of more than 50 lacs and doing many minor research and consultancy projects for the herbal drug industry and research centers. Being a recognized PG/Ph.D. guide, guided more than 29 M. Pharm & 12 M. Sc Cosmetic technology students, 4 PhD students have been awarded and 2 are pursuing Ph. D at Nirma University under her able guidance. She is a recipient of P.K. Debnath Memorial Award: SFE Young Ethnopharmacologist Award 2020 for Best Oral Presentation in the field of Ethnopharmacology and medicinal plant research, GABTP national woman scientist award 2019 at 29th APSI scientist meet and international conference on Drug discovery and development in Agrobiotechnology and Pharmaceutical sciences, Best research paper award at the International Symposium on Cancer research at GCRI in 2014 and Dr. P.D. Sethi's research paper award 2006. The research area of her interest includes phytopharmacology based investigations & characterization of biomarkers from medicinal plants for the management of neurodegenerative disorders like Alzheimer's disease, wounds, obesity, liver disorders. She has been working on development of novel and target-based delivery for natural bioactives across blood brain barrier and wounds. She is a life member of various professional bodies like American Society of Pharmacognosy, APTI, ISP, IPA, ISTE, Society of ethnopharmacology, Indian Academy of Neurosciences, IPGA and has been working as an editorial member and reviewer for many journals of Elsevier, Taylor and Francis and Willey.

Dr Nagja Tripathi

Dr Nagja Tripathi is working as an Assistant Professor in the Department of Pharmacognosy. She has about 20 years of experience which includes 16 years of teaching experience and 4 years of industrial experience. She has worked in Quality Assurance, Formulation Development and Quality Control departments of reputed pharmaceutical companies like Cipla and Sanofi Aventis. She has presented several scientific posters in various national & international conferences and published several papers in reputed journals. She has completed two minor research projects funded by Nirma University. She is a life member of various professional bodies like APTI (Association of Pharmaceutical Teachers of India), Society of Pharmacognosy and Indian Society of Technical Education (ISTE). Her research

interest is phytopharmacological screening & standardization of herbal drugs, development of herbal formulations and herbal cosmetics. She is a recognized PG and PhD guide at Nirma University.

Dr Dipal Gandhi

Dr Dipal Gandhi is working as an Assistant Professor in the Department of Pharmacognosy. She has more than 13 years of academic experience and also worked as a senior research fellow with BV Patel PERD research center. She has received Dr. P. D. Sethi's memorial award for best research paper on Application of TLC/HPTLC in Pharma, Herbal and other chemical analysis by Anchrom enterprises India Pvt. Ltd in 2019. Her area of interest is mainly in Phytochemical Investigation, standardization and quality control of herbal drugs, analytical method development of phytoconstituents and evaluation of their pharmacological activity. She has published 8 papers in reputed national and international journals. She has attended many national and international level conferences, QIP, FDP, STTP and presented several posters in many national and International conferences. She has guided 15 postgraduate students as Research Guide/Co-Guide. She is a life member of professional bodies like the Association of Pharmaceutical Teachers of India (APTI), Indian Pharmaceutical Association (IPA), Indian Society of Pharmacognosy (ISP), ISTE and Indian Society of Chemists and Biologists (ISCB).

MANAGEMENT & STAFF

University Management

Name	Designation
Dr Karsanbhai K. Patel	President, NU
Shri K. K. Patel	Vice President, NU
Dr Anup Singh	Director General, NU
Shri G. R. Nair	Executive Registrar, NU
Prof P. N. Tekwani	Dean, Faculty of Doctoral Studies and Research (FDSR), NU
Dr. Rajesh Patel	Additional Director, Institute of Technology
Prof Subir Verma	Dean, Faculty of Management Director, Institute of Management
Dr. Hrudanand Misra	Additional Director, Department of Undergraduate Studies, Institute of Management
Prof. Tejal Mehta	Dean, Faculty of Pharmacy Director (I/c), Institute of Pharmacy
Prof Sarat Dalai	Dean, Faculty of Science Director, Institute of Science
Dr. Madhuri Parikh	Dean, Faculty of Law I/c Director, Institute of Law
Prof Utpal Sharma	Dean, Faculty of Architecture & Planning Director, Institute of Architecture & Planning
Prof Udai Paliwal	Director & Dean, Faculty of Commerce
Prof Sangita Shroff	Director & Dean, Faculty of Design
Shri Ashishbhai Desai	Hon. Head of the Dept. of Students' Activities
Prof Tejal Mehta	Deputy Director, Centre for Quality Assurance and Academic Development (CQAAD) cell, NU

University Department Head

Name	Designation
Ms. Palak Shah	Chief Accounts Officer
Dr Nilesh M. Patel	Deputy Registrar, Examinations and PhD Section
Dr Ravindra Sen	Deputy Registrar, Academic and Establishment
Dr Bhaveshkumar Parekh	Coordinator, Students Welfare Board
Shri Alok Bhatnagar	Public Relation Officer

Non-Teaching Staff Members

Name	Designation
Ms. Telgy James	Office Superintendent
Ms. Vicky Takhtani	Corporate Relation Manager
Mr. Virendra Goswami	I/c. Librarian, IP
Mr. N. Nityanandan	PA to Director
Mr. Hasmukh B. Rathod	Assistant
Ms. Pooja P. Pandey	Assistant
Ms. Jigisha D. Patel	Assistant
Mr. Devendra Vaghela	Assistant
Ms. Jaya Dabhi	Library Assistant
Ms. Kinjal Parekh	Library Assistant
Mr. Rohit Patel	Laboratory Assistant
Mr. Mukesh Patel	Laboratory Assistant
Mr. Shailesh Patel	Laboratory Assistant
Mr. Jignesh Patel	Laboratory Assistant
Ms. Dharti Patel	Laboratory Assistant
Mr. Chetan Patel	Laboratory Assistant
Ms. Drashti Patel	Laboratory Assistant
Ms. Hiral Patel	Laboratory Assistant
Ms. Kalpana Patel	Laboratory Assistant
Ms. Dharmi Shah	Computer Operator

INDUSTRY INSTITUTE INTERACTION CELL

Objective of Industry Institute Interaction (III) Cell is to constantly interact with industry so as to maintain healthy and mutually beneficial relations between industry and academia. III Cellworks towards providing close links with pharmaceutical industries, contra ct research organizations and other state and national level R&D organizations so that it helps the institute in student placements / training / Curriculum improvement etc. It strives to find out the gap between the needs of the industry and the end product of the Institute. III Cell tries to facilitate and enhance quality of interaction between the institute stakeholders and Industry.

At Nirma University, each institute has its III cell, which is managed by a dedicated Corporate Relations Manager. It is supported by faculty placement coordinators and student coordinators, working under the guidance of the Director and in association with respective heads of the departments. III Cell facilitates student visits to industries, industrial training, project, campus interviews & placement. Placement of students for industry training/projects during summer has been benefiting students to a great extent.

It trains and grooms the students so as to ensure that students can smoothly transit from academics to industry. The students are oriented and trained towards placement related topics like writing better resumes, participating in group discussions, facing interview, interview etiquettes etc. With the efforts of III cell, the students of recent years pass out batches have been placed in companies like Torrent Research Centre, Novartis, Nestle, Sun Pharma, Sanofi India, Amneal Pharmaceuticals, Troikaa Pharma, Eris Lifesciences, Zydus Cadila, Piramal Healthcare, Intas Pharmaceuticals, ELC group, Lambda Therapeutics, APCER Lifesciences, Cadila Pharma, Johnson & Johnson, Rusan Pharma, Allen Career Institute, Finecure Pharmaceuticals, etc.

Industries Involvement in Course Curriculum Design

In various academic bodies, there is adequate representation of industry experts which makes the curriculum rich and relevant to industries. Participation of experts from the pharmaceutical industry is regularly helping us in designing and updating the curriculum. Portions of the syllabus are also covered by Industrial experts to enhance their knowledge.

Industrial Training for the undergraduate and postgraduate students

Training is an integral part of the study to prepare the students for the real world problems. The undergraduate and postgraduate students are supported for internship at various industries for 6 to 8 weeks under the supervision and guidance of respective industry personnel. The faculty carries out monitoring and evaluation regularly.

Placement cell

Placements play an important role in meeting the career aspirations of each student enrolled in the programme. In its endeavor to assist students in meeting his/her career goals, the Institute has a well-equipped and organized Placement Cell, which is in constant touch with the industry so as to create better placement opportunities for students.

Final Placement

The Institute helps each student in exploring placement opportunities by inviting various companies for campus recruitment of students who are in the final year of the programme and are likely to graduate at the end of the academic year.

The final placements, at the Institute, are a result of very systematic interaction with the industry and continuous career counseling of the students. Right from the beginning of the programme, students are continuously counseled with regard to his/her career aspirations and options, which in turn is vigorously followed up with the potential companies for participating in the placement programme of the Institute. This not only helps the students in getting their 'dream' jobs but also assists the visiting placement companies in identifying the 'right' candidate for their organization. However, the placement will be governed by Placement guidelines.

Planning for Placement

The placement activity is primarily managed by the Placement Committee headed by Director of the institute as Chairperson with the help of the Manager Corporate Relations and other committee members which includes faculties and students from various departments.

The Broad Activities Undertaken by the Placement Cell are*:*

- Formation of students' placement committees for final placement and also for getting industrial training and industry linked project work for students.

- Grooming and training of the candidates for the placements so that their chances of selection increase.
- Preparation of placement brochure for final placement.
- Communication, networking and relationship building with the potential recruiters
- Pre-placement visits (PPV) to the companies.
- Invitation to potential recruiters to visit the Institute.
- Continuation of placement activities after the stipulated period, till all the students are placed.
- General follow-up, joining formalities and other administrative activities.

Institute Placement Committee

The placement related activities, at the Institute, are carried out by Placement committee – it comprises faculties from various departments of the institute. Student representatives from various branches who are in their final year are also appointed as committee members. The committee is headed by the Director of the Institute and Manager Corporate Relations acts as a member secretary. The placement committee is usually formed in the month of July.

Student Registration for Placement

The students who are in their final year and interested in availing placement support from the institute, will have to register themselves for placement. Those who don't want any kind of placement support need not register themselves. Registration for placement is done by paying placement registration fees decided by the institute from time to time.

Placement Brochure

The Institute prepares a placement brochure, giving details of the students ready to be placed for the benefit of the students and potential recruiters. This brochure is subsequently shared with potential recruiters. The students registered for placement are included in this brochure.

Placement Eligibility

Students who fail to clear the academic exams & other formalities at the end of course, shall be removed from the placement process and hence will not be eligible for campus placement activities. Any major disciplinary actions will terminate the student from campus placement activities

Placement Process

Once an organization shows interest in recruitment from the Institute, the students are asked to register their interest for the job. An email informing about the job opening and its details will be shared with the student coordinators and placement committee. Placement cell will try to get as many details as possible about the job profile. The registration of interest is to be done by students from their official Nirmauni ID on the provided link, after going through the job profile. It is not compulsory. Only students who register for that particular job profile will be considered for the job opening and their names and CVs will be shared with the company. It will be the responsibility of a student to keep his/her resumes updated with the placement cell. Once the names of students are submitted, students are not allowed to withdraw from the selection process.

Sometimes companies come for Pre-Placement Talk / Group Discussion / Written Test and the short-listed students are interviewed at the campus or off the campus. Alternatively, some companies select students based on their CVs and may invite them for Group Discussions/Interviews at their offices.

Guidelines for Placements

The final placement is governed by certain guidelines, which are framed to facilitate the students to get maximum benefits:

These guidelines are revised from time to time. The guidelines being followed currently are:

1. If a company is coming for a Pre-placement talk, attending a Pre-Placement talk is compulsory for all the students unless informed otherwise by the student in writing.
2. A student can only withdraw his/her name before the CVs are sent to the company.
3. Under no circumstances, the students will personally communicate with the companies (except those who opt for private placements). If a student breaches this code, he/she may be debarred from the final placement at the campus.
4. If the company shortlists/selects a student on the basis of his/her CV, the student has to go through the next steps of the selection process.
5. In case a student opts out after getting short-listed by the company, he/she will not be eligible for final placements through campus.
6. Students once finally selected by a company through campus placement shall not be considered for placement in future at the campus.
7. Students have to wear formal dress during the PPT, Group Discussions and Interviews.

8. The eligibility of a student, who can apply for the selection in a company, will be determined based only on the specifications/ job profiles offered by the company and as directed by the respective companies.
9. The Placement cell will try to bring and put forward as many details as possible for the job openings to the students. Students are not permitted to ask for location preferences or negotiate on salary, if it is already disclosed by the company.
10. The Institute will not interfere in the selection process of the visiting companies.
11. A student can appear for placement for any number of companies until he/she gets selected, and after selection shall not be eligible to appear for placement in any other company.
12. In case a student has appeared for more than one company before the declaration of the result, the student has the option to select the company of his choice from the results of the other companies for which he/she has already appeared on that particular day. This clause is applicable only if one is through the interview process (full selection process) of two or more companies simultaneously.
13. In case, if one has appeared just for written test process of company A, before appearing

    for an interview, and he /she has got selected in some other company, then he / she will not be allowed to appear for further selection process of company A.
14. The student who receives an offer letter from the company shall join the company as per terms of offer letter.
15. In a batch, when we reach a level of 75 % placement, for the students remaining to be placed, they will NOT HAVE the right to exercise their choice and sit for selective companies. He/she has to sit for all companies which they qualify for. However, students who submit their reservations (example: location, remuneration, industry/company, and profile) will not be forced / allowed to sit for those specific profiles, companies, location and remuneration.
16. Institute will try to place those students suitably who have specific industry / job preferences / location constraints, etc. In case, if these students remain unplaced after the completion of the programme, the Institute for all official records will consider them placed.
17. Students noticed to be underperforming deliberately will be put out of the placement process for the next 5 companies. (Under performance will be verified through the feedback from the company officials)

18. All communication related to placements / job openings will be done on the email Id registered with the placement cell. It is the student's individual responsibility to check the emails on a regular basis.
19. It will be the responsibility of a student to keep his/her resumes updated with the placement cell. If any falsification of data or serious misrepresentation of information is found in the CV or registration details of a candidate which may influence the chances of selection, he/she will be immediately removed from the placement process.
20. It is obligatory for each student to abide by the rules/guidelines as stated above, failing which he/she shall be debarred from the placement process of the Institute. However in the interest of the Students / Institution and corporate relations the placement cell has the discretion to make changes in the above guidelines/rules. In case of any doubt or dispute, the decision of the Chairperson of the placement committee will be final. No coercion by any student (s) will be allowed at any level. The Chairperson’s decision will be final and irrevocable.

PLACEMENT SUMMARY 2017 - 2021

GENERAL RULES & REGULATIONS

	2017		2018		2019		2020		2021	
	Placed	Interested Students	Placed	Interested Students	Placed	Interested Students	Placed	Interested Students	Placed	Interested Students
M.Pharm – Pharmaceutical Chemistry	-	-	1	1	4	5	2	2	4	4
M.Pharm - Pharmaceutical Analysis	6	6	-	-	5	6	8	8	9	9
M.Pharm - Pharmaceutics	10	10	13	14	9	9	9	10	11	13
M.Pharm – Pharmacology	4	4	9	9	9	10	11	11	8	8
M.Pharm – Regulatory Affairs	12	12	13k	13	8	8	9	10	8	8
M.Pharm	**33**	**33**	**43**	**44**	**35**	**38**	**39**	**41**	**40**	**42**
B.Pharm	**8**	**10**	**6**	**7**	**10**	**10**	**13**	**15**	**10**	**11**
Grand Total	**41**	**43**	**49**	**51**	**45**	**48**	**52**	**56**	**50**	**53**
Ph.D Students Placed	-	-	3	3	-	-	-	-	-	-
% students placed out of students interested for placement *	95.34%		96.07%		93.75%		92.85%		94.33%	

Attendance

Guidelines for Students

- The students are required to attend all the classes, Practical work, Tutorials conducted throughout the day.
- In every course, attendance will be taken by the course coordinator / faculty in-charge of the class. Mere attendance is not the objective but positive interaction and learning environment is a given expectation from the students.
- Attendance will be taken in the first 10 minutes of the class. Students have to be present in the class before the faculty enters. If students enter later then they will not be granted attendance under any circumstances.
- Students are required to seek prior permission from the Director / HODs for remaining absent from any of the classes, Practical work, Tutorials by submitting leave application available with PA to Director. Absence without prior permission would be treated as an indisciplined act and will be processed accordingly.
- In case of any emergency/ medical reasons, if students are not able to seek the prior permission, they are required to intimate to the Director the reasons for remaining absent through email (director.ip@nirmauni.ac.in). In case of leave due to medical reasons, an application along with medical certificate and test reports is to be submitted within three days after the student resumes the Institute to the attendance committee coordinator.
- As per the University regulations, students are required to attend 85% of the classes conducted in each course. However the Director of Institute may consider upto 65% attendance with valid reasons for absence and the appeal committee appointed is convinced with the reasons provided by appealing student for his/her absence. However, in no case any student should be permitted with less than 65% attendance even with valid reasons.
- First attendance review will be taken in the mid of the semester and final attendance review will be taken at the end of the semester. Students having a shortfall in the attendance, will be called in the appeal committee. The Appeal Committee will hear the candidates and decide the case accordingly.
- Prior permission of the Director shall be obtained for availing of Duty Leave in the form of a leave application from the Director's office. For attending seminars / conferences / workshops / competitions / any other events outside the institute / any personal functions, a duty leave application must be submitted with proofs normally prior 3 days to the commencement of the leave. The duty leave along with necessary

documents is to be submitted to Ms. Poojaben (Student Section) within three days after the commencement of the event.

- Students have to take permission from the Faculty Coordinator of the respective event for publicity of the events.
- Attendance related to practicing for any type of event will not be considered.
- By looking at the large number of participation from the same students in various events outside the institute, it was decided that the participants will be restricted maximum three times outside the institute / university for the same students in the respective semester.
- Sanctioned Leave will be credited to the attendance of the students at the time of final review.
- The Institute will not be responsible for the student losing any component of assessment on account of his leave.

Class Conduct

- The students are expected to be in the classroom at least five minutes prior to the commencement of the class. Unpunctuality is not acceptable.
- Students are expected to come prepared to the class with the readings/ chapters and cases mentioned in the course outline for the session. The student may be asked to leave the class if he/she is not fully prepared for the session.
- Use of mobile phones is strictly prohibited in the classrooms, corridors and inside the blocks. Violation would imply confiscation of the mobile phone.
- Students are expected to behave in a responsible manner and abstain from chatting amongst themselves while the class is in progress.
- Activities like video shooting, photography, playing musical instruments and listening to radio and tape recorders are prohibited in the campus.
- Any indiscipline or misbehaviour in class would warrant disciplinary action against the student.

Learning Resources Centre (Library)

At the Institute of Pharmacy, it is a belief to facilitate production and dissemination of knowledge, information, insights & intellect in all scientific communities. The library plays a vital role in the collection, development and dissemination of scientific information and includes a wide range of volumes in different branches of Pharmaceutical Sciences and allied

subjects and also provides extensive access to leading Indian and international research journals.

The Library at the Institute of Pharmacy houses more than 9,476 volumes of books selectively chosen for reading and reference, 367 CDs, 1,835 Bound Volumes, 1036 Project Reports (B.Pharm), 646 Research Project Reports (M.Pharm), 98 PhD Theses and subscribes to about 22 printed national, 1 international periodicals, 6 magazines and 8 newspapers. The library also provides Web access to 211 e-journals: Science Direct: Pharmacology, Toxicology and Pharmaceutical Sciences Module (87), InfoTrac Pharmacy Collection (IPC) - Cengage Gale Database (116), Royal Society of Chemistry Journals (3), Springer Journals (2), International Journal of Pharmaceutical Sciences and Nanotechnology (1)**,** Journal of Health Management (1) and Pharmacological Review (1).

Online Resources

Science Direct, web-based interface to the full-text database of Elsevier Science journals one of the world's largest providers of scientific, technical and medical (STM) literature offers a rich electronic environment for research journals, bibliographic databases and reference works. We have unlimited and complete online access to 87 journals *(Pharmacology, Toxicology and Pharmaceutical Science)* of Elsevier Science available in the Science Direct database.
Resource: 87 journals published by Elsevier Science
Back-files: 1997 onwards
Simultaneous Access: Unlimited
Click here: http://www.sciencedirect.com/

The InfoTrac Pharmacy Collection (IPC) - Gale Database is designed for students, scholars and teachers of primary and core pharmacy research. This collection covers many subject areas, including Human Anatomy and Physiology, Therapeutics, Dispensing pharmacy etc.
Resource: 116 journals
Back-files: 2000 onwards
Simultaneous Access: Unlimited
Click here: https://infotrac.gale.com/itweb/ipnu

The Royal Society of Chemistry publishes one of the world's leading journals covering the entire spectrum of chemical sciences and related fields.Known for rigorous, fair peer review

and fast publication times, journals publish the best science, from original research articles to authoritative reviews.
Resources: 3 journals
Back Files: 2009 onwards
Access: Unlimited
Click here: https://www.rsc.org/

The Springer publisher focuses on the fields of pharmacy, nursing, gerontology, psychology, social work, counseling, public health, and rehabilitation (neuropsychology).
Resources: 2 journals
Back Files: 2007 onwards
Access: Unlimited
Click here: https://link.springer.com/

The International Journal of Pharmaceutical Sciences and Nanotechnology (IJPSN) is an internationally circulated research journal in the pharmaceutical and nanotechnology fields.
Resources: 1 journal published by Pharma Book Syndicate
Back Files: 2008 onwards
Access: Unlimited
Click here: https://www.ijpsnonline.com/index.php/ijpsn/about/subscriptions

The Journal of Health Management is designed as a forum for exploring major issues of health policy and health management (including population and family welfare) in developing countries with a view to assisting the better implementation of desired changes. It caters to the needs of health policy-makers, health managers, reflective practitioners and action-oriented researchers.
Resources: 1 journal published by Sage Publisher
Click here: https://journals.sagepub.com/home/jhm

Pharmacological Reviews showcases important review articles on topics of current interest. Topics covered are biochemical and cellular pharmacology, drug metabolism and disposition, renal pharmacology, neuropharmacology, behavioral pharmacology, clinical pharmacology, and toxicology.
Resources: 1 journal published ASPET
Back Files: 1997

Access: Unlimited

Click here: http://pharmrev.aspetjournals.org/

Automation

The Library and Resource centre is fully automated with Open Source, user-friendly library software KOHA that facilitates automated circulation (issue & return) of books and location and availability information of the books stocked in the library. Online Public Access Catalogue (OPAC) is also available on the Internet to inquire about the status of the resources. To computerize the bibliographic details of the resources, a bar-coding system is used.

Facilities and Services

The Library & Resource Centre offers the following facilities and services:

Facilities:

- Photocopying
- Online Public Access Catalog OPAC (Computerized Information Search)
- Internet browsing
- Book Bank
- Library Mobile Apps

Services

- ➢ Reading /Reference
- ➢ Circulation
- ➢ User Education Programmes
  - Library Orientation Programme
  - Information Literacy Programmes
- ➢ Current Awareness Service
  - New Arrival Lists of Books and Periodicals (Display on Notice Board as well as
  - through Emails)
  - Newspaper Clipping
  - Current Content Alerts through RSS feeds
- ➢ Selective Dissemination of Information (on demand service)
- ➢ Examination Papers Depository on Google Drive

- ➢ Digital Library (Institutional Repository)
- ➢ Interlibrary Loan
- ➢ Remote login

Other Activities

- ➢ Screening TED Talks
- ➢ Book Review
- ➢ Celebration of National & International Days
- ➢ Literature Club (Gyan Samhita): - intended to bring out the literary talents of the students
- ➢ Training of Zotero & Mendeley (Reference Management Software) for IPNU Users.

Learning Resource Centre Rules and Regulations-

Rules for Book Loans for Students

- The Library Issue/Return counter will be open from 9.00 a.m. to 6.00 p.m. only.
- Students are supposed to show their library usage by entering their roll number on the Check Counter whenever they come into the Library
- B. Pharm / M. Pharm Students can borrow three books at a time for the period of 10 days on their Identity Card and Research Scholars can borrow five books for a period of one month. Books will be renewed once only if there is no reservation for it.
- Library resources like Reference Books, Periodicals, Bound Volumes, Standards, CDs, and Audio/video Cassettes are to be referred within the library premises.
- Students can issue a reference book for overnight period (Overdue Charge Rs. 100/- per day per book) and two backdated issues of general magazine for two days (Overdue Charge per day Rs. 5/- per magazine).
- Before borrowing the book, he/she has to verify the physical condition of the book. If he/she finds the physical condition of the books bad, he/she must inform Librarian's immediately.
- It is the borrower's responsibility to keep the book and return it to the library, but if a student loses or misplaces the book, he must report it to the librarian on the same day. He will have to clear his library account by either replacing the book or by paying the cost within a week. If he/she fails to do so, not only the cost of the book, but also overdue will be recovered from the student.
- Borrowers will be responsible for any damage found while returning books.

- Students will have to return the borrowed books on time. The overdue charge is Rs.2/- per day.
- If any student's card is lost, he has to report to the Librarian immediately and operation of the account will be in abeyance until he gets new.
- If students are going on a Short-term industrial visit or project, they have to maintain the schedule of returning the books. This rule can be relaxed on the recommendation of the HOD for borrowing books for his project, when a student is deputed for a project for the entire semester out of Ahmedabad.
- If any student is caught, stealing books or tearing pages will have to pay the entire cost of the books plus Rs.500/-. And Library Account will be suspended for two months in addition to the disciplinary action to be initiated.
- If any book lost by any student, not available in the market, he/she is required to pay three times the original cost. The A/c has to be cleared within two weeks at least.
- If any student misplaces/loses any complimentary copy, the HOD will decide the amount to be paid by the student after consulting the subject expert.
- To maintain Discipline and Silence in the library is mandatory. If any student fails, then he/she will be penalized / punished.
- If students violate library rules, their identity cards will be collected and reported to the institution's head in order to initiate disciplinary action.

Rules for Book Reservation for Students

- Users can reserve books from their library account through the online library's OPAC or reservation forms can be obtained from the Library Check Counter.
- To make a reservation through the online Library OPAC, click on the place on hold icon.
- Only Issued (Checked Out) books can be reserved through your library account of Library Software.
- Users can reserve and cancel any title or book which is not available in the Library.
- Books can be collected within two days after their arrival at the library.
- If you do not collect books within said period, your reservation may be treated as cancelled.

Rules for Book Bank Facility

The Library Resource Center provides a book bank facility for the students of the Institute of Pharmacy. The primary goal of this service is to assist needy and deserving students.

- The book bank facility will be given to the 10 % students of the total strength of each Semester on the basis of the income of their parents and the ceiling of the same will be Rs.6.00 lakhs per annum.
- Depending upon the availability of the sets of books, priority will be given to the students on the merit of the last examination.
- If a student fails the Semester End Examination, he or she will be ineligible for the Book Bank Facility.
- 10% of the book value (set of textbooks) is to be taken as maintenance charges from all the categories of students who are selected for the Book Bank Facility.
- All students who are using the facility must ensure that they return the entire set of books provided to them within two days of completion of their final examination in the concerned semester/term.
- The overdue charge is Rs.2/- per day per book.
- If any student availing of the facility loses the book / damages the book / disfigures the book, he / she shall replace the volume(s) with new books (or pay the current cost of the book plus a fine, if any, as may be directed by authorities).
- The cost of this application form is Rs.10/-.

Library Suggestion

- You are welcome to give suggestions for the improvement of the library services and collections.
- You are free to give your valuable suggestions to us.
- The Library Suggestion Register is available at the library check counter.
- You may see the status of your suggestion on the Library Notice Board or in the suggestion register.

Library Users are asked to strictly follow the below given points.

- Silence should be maintained in the Library Premises.
- Mobile phones are prohibited within the library premises.
- Keep library books in their proper place/on the table.
- Handle all the library materials with care.
- It is forbidden to spoil or damage library materials.
- They are not permitted to bring their own reading materials or issue books to the library.
- It is not permitted to bring personal floppy disks, CDs, or DVDs to the library. With the permission of the library staff, students may copy library CDs and DVDs.

- Failure to follow the above rules on a regular basis will result in the library's membership being terminated.
- If they have any problems, they can contact the library staff at any time.
- Give Suggestions to Improve Library Services.

Timings

Opening – Closing Hours: 08.45 am - 06.15 pm (Monday – Friday)

08.45 am – 4.45 pm (1st, 3rd & 5th Saturday)

Issue/Return Counter: 11.00 am – 06.00 pm

09.00am – 4.30pm (1st, 3rd & 5th Saturday)

Photocopying Service: 11.00 am - 01.00 pm

Please log on to **http://pharmscilibrary.nirmauni.ac.in/** to know more details about the library.

In addition to the Institute of Pharmacy Library resources, students and faculty could access the digital resources of the University from the same homepage.

Computer Laboratory Rules

General

- Misuse of Internet/Intranet mail service will invite strict disciplinary action.

For the usage of Computer Lab

- Students should make an entry in the log register.
- Students should not change properties/configuration of the client machines.
- Students should keep silence and observe discipline while working.
- Students should not leave rough papers on desks.
- Students should not eat or drink in the computer centre.
- Pen drive is prohibited in the computer centre.

* ACADEMIC REGULATIONS FOR POST GRADUATE DEGREE PROGRAMMES (M. PHARM.) UNDER FACULTY OF PHARMACY

DEFINITIONS

PROGRAMME	--	M. Pharm. (Programmes as per Annexure 1)
COURSE	--	One of the constituent subjects of the Programme
SEMESTER	--	Duration for studying a course
TERM	--	A portion of an academic year, normally coinciding with a semester. The words "Term" and "Semester" are generally used synonymously.
REGISTRATION	--	Procedure for getting enrollment in a course
LETTER GRADE	--	A letter associated with a particular performance level of the student. A qualitative meaning and a numerical index are attached to each grade. A+ to C+ are Passing grades, C -- Conditional pass, FF -- Fail, IF – Interim fail
CREDIT	--	A numerical figure associated with a course. On passing the course, the student earns this "credit".
GRANTING A TERM	--	This expression is used to indicate whether the in-semester performance of the student is up to acceptable standards. GT – Term granted, NT – Term not granted
REGULAR APPROVAL	--	If a student is unable to attend the institute or appear in an examination on account of unavoidable reasons like illness, accident or unforeseen circumstances, prior / prompt intimation and request to HOD is necessary for seeking approval for the absence. The approval of HOD so obtained will be referred as Regular Approval.

SHORT FORMS

Institute of Pharmacy	--	Institute
Director of Institute of Pharmacy	--	Director
Dean of the Faculty of Pharmacy	--	Dean
Head of concerned Department	--	HOD
Appeal Committee consisting of	--	Appeal Committee consisting of Director, Dean & Two Senior Faculty Members nominated by Director

* Published vide Notification no. NU-318 dated 3.8.2004, AC mtg.-8.7.2004, reso.-3(a)&(b), read with Notification no. NU-884 dated 10.3.2005, BoG mtg.-5.2.2005, reso.-7

Initial Registration	-- IR
Repeat Registration	-- RPR
Repeat Registration for LPW	-- RL
Repeat Registration for studying all components of a course	-- RS
Term Not Granted	-- NT
Re-examination Registration	-- RER
Re-examination registration for CE component of a course	-- REC
Re-examination registration for SEE component of a course	-- RES
Continues Evaluation	-- CE
Laboratory/Project work	-- LPW
Semester end examination	-- SEE
R. Pharm. (PG)	-- R.

R.PHARM. (PG) 1. PROGRAMMES

The Post Graduate Degree Programmes in Pharmacy, leading to the degree of Master of Pharmacy, are offered by Nirma Institute of Pharmacy. All Programmes are full time minimum of two years duration and are approved by Nirma University.
Intake: To be decided by the Academic Council from time to time

R.PHARM. (PG) 3. CATEGORIES OF COURSES

The following categories of courses are offered in the programmes.

3.1 CREDIT COURSES

These are compulsory courses. They are included in the schedules of various semesters. Credits earned for these courses will be considered for evaluating the academic performance levels of the student.

3.2 SUPPLEMENTARY COURSES

These courses will be offered as and when necessary. They are compulsory courses. They are not included in the schedules of the semesters but are shown as additional courses, wherever applicable.

No credits are assigned to these courses. However performance in these courses will be considered while deciding continuation of the student in the Programme or his registration in higher semester.

NOTE**:** Hereafter, the Credit Courses will be referred to simply as “courses”. Supplementary courses will be specifically mentioned as such.

R.PHARM. (PG) 4. COMPONENTS OF A COURSE

The academic schedule of the courses may consist of one or more of the following components with their respective scope as described.

- LECTURES (LECT) - Teaching learning processes conducted in real and virtual class rooms with various multimedia aids.

- TERM ASSIGNMENTS (TA) - Supplementary to classroom teaching. It consists of one or more of the following teaching strategies.
  Each strategy will form a UNIT.

  Self-study exercises/quizzes/tests/objective questions/viva term paper, case study analysis, seminars etc.

- LABORATORY WORK / PROJECT WORK (LPW) -This component consists of one or more of the following practical exercises / projects.
  Each set of practical exercises / project will form a UNIT.
  Laboratory experiments and their reports.
  Viva, Synopsis, Seminar, industrial / professional training, analysis, design, research problems, Thesis work etc.

R.PHARM. (PG) 5. EXAMINATIONS

For assessment of the course, Examination/s are prescribed for each component.
These examinations are as follows.

LECTURES	--	Semester End Examination (SEE)
CONTINOUS EVALUATION (CE)	--	CE examination may include written examination/s and Term Assignments (TA) Examination
LABORATORY/PROJECT WORK	--	LPW examination

R.PHARM. (PG) 6. COURSE COORDINATOR, ADVISOR

The Dean will appoint faculty members for the following designations. The main functions of each designation are also mentioned.

- COURSE COORDINATOR (to be appointed for each course) – to coordinate all matters related to the conduct and assessment of a course.

- FACULTY ADVISOR (to be appointed for each semester) – to look after all matters, at the department level, regarding Registrations and Re-registrations of courses and also to provide guidance and counseling to students regarding these issues.

R.PHARM. (PG) 8. SEMESTER AND TERM

Normally courses will be offered semester-wise as given in the teaching scheme. However the institute may offer certain course/s of a semester in both terms of an academic year in order to help students to pursue their study more expeditiously.

R.PHARM. (PG) 9. REGISTRATION IN COURSES

9.1 There will be five categories of Registrations. All five categories will be collectively referred to simply as Registration. Individual categories will be referred to by their symbols.

9.2 All Registrations, wherever applicable, will be subject to availability of courses.

9.3 Registration will be done course-wise.

9.4 CATEGORIES OF REGISTRATION

9.4.1 The Five categories of Registration are:

IR – Initial Registration

RPR – Repeat registration with two sub categories RL (Repeat registration for studying LPW component of a course) and RS (Repeat registration for studying all components of a course)

RER – Re-examination registration with two sub categories REC (Re-examination registration of CE component of a course) and RES (Re-examination registration of SEE component of a course.)

9.4.2 Initial Registration (IR) - In order to study a course for the first time, the student will register under the IR category. This will imply regular attendance for study of all components of that course and appearing at all examinations thereof. IR registrations for courses of a semester are to be done for ALL courses of that Semester as shown in the Teaching Scheme; IR registration will not be permitted for lesser number of courses. The student who so registers (IR) for all courses of a semester will be considered as having been registered in that semester.

New entrants admitted to the programme on the basis of HSCE or equivalent will register (IR) for the first semester.

Diploma students admitted to the Degree programme will register (IR) for the semester as notified by Nirma University.

9.4.3 Repeat Registration (RS)

The student whose Term is not granted for any registered course (R.12) will have to repeat the study of that course. He will have to seek fresh registration for this purpose. The category of such registration will be as follows:

Term not granted	Registration
Category	Category
NT	RS

RS - This category will imply regular attendance to study all components (i.e. LECT, CE, LPW as applicable) and appearing at all examinations thereof.

9.4.4 RE-Registration (RER) **-**This registration is necessary for appearing again in a particular examination of a course. It will not involve regular attendance for studying that course.

9.4.5 RPR Registration **-**This term will be used where necessary to include registrations of both categories RL and RS.

9.5 APPROVAL OF REGISTRATION

Every student must apply in the prescribed form for registrations, as applicable. The decision on the student's request will be based on the availability of courses and applicable Regulations. The Director will issue appropriate orders for processing the application, including scrutiny, verification and final orders.

9.6 SIMULTANEOUS REGISTRATION IN DIFFERENT CATEGORIES

9.6.1 Semesters will be registered in chronological order.

9.6.2 A student will not be permitted to register (IR) in the next higher semester if the total number of courses with RER and/or RPR as applicable in his case exceeds three.

9.6.3 The student who becomes eligible for IR registration in a higher semester must first register for all RER and RPR registrations as applicable in his case.

9.6.4 The student who is not eligible to register in a higher semester in any term must register in that term, for all RER and RPR registrations applicable in his case.

R.PHARM. (PG) 10. GRADES

PERFORMANCE LEVELS

The Performance level of the student in any examination will be adjudged in terms of the letter grades given in Table 1.

Table 1

Grade Qualitative (G)	Equivalent Meaning (GQ)	Grade Point (g)
A+	Excellent	10
A	Creditable	9
B+	Very Good	8
B	Good	7
C+	Satisfactory	6
C	Conditional Pass	5
FF	Fail	0
IF	Interim Fail	0

R.PHARM. (PG) 11. SCOPE OF EXAMINATIONS AND ASSESSMENT

In order to pass a course, the students will have to pass all examinations of that course. The scope of the examinations and the method of assessment will be as follows.

11.1 In all mark based assessment, the overall percentage marks, if fractional, will be rounded off to the next higher integer value.

11.2 TA AND LPW EXAMINATION (IR and RPR)

All exercises in CE will be continuously assessed during the semester and given marks. Oral examination will be included in the assessment at all possible stages. The total marks of all Units of CE will be aggregated based on their *inter se* weights to give the overall percentage of marks in the CE examination.

If the student fails in CE examination, the student will not be permitted to appear in SEE of that course and the student will have to seek fresh registration. as REC in subsequent semester, if the student is otherwise eligible.

11.3 LPW EXAMINATION (IR and RL/RS)

All assignments in Laboratory / Practical Work will be continuously / periodically assessed (as applicable) during the semester. In addition, there will be an Examination for overall assessment at the end of the semester. Oral examination will be included in the assessment at all possible stages. Each assessment will be given marks. The total marks of all Units of LPW will be aggregated based on their *inter se* weights to give the overall percentage of marks in the LPW examination.

The course coordinator will notify the procedure for assessment, review, viva voce etc to the students in advance.

If the student fails in LPW examination, the student will not be permitted to appear in SEE of that course and the student will have to seek fresh registration. as RL in subsequent semester, if the student fulfills the condition of granting the term (R-12)"

11.5 SEMESTER END EXAMINATION (SEE)
(IR and RPR)

The expression "Semester end examination" refers to the written examination of a course taken at the end of a semester. This will cover the full syllabus.

The assessment will be mark based as per normal practice in written examinations.

11.6 SCHEDULES OF SEE

SEEs of all courses of the programme, as per the teaching scheme, will be held at the end of both terms.

11.7 Absence in any examination with or without Regular Approval will be assigned Zero mark.

R.PHARM. (PG) 12. GRANTING OF TERM

15.1 The Term will be granted course-wise.

15.2 The granting of Term for all the students (IR, RPR) will depend on the compliance of maintaining minimum 85 % attendance in all components of the course (as applicable) Regular approval for remaining absent up to 15 % is necessary.

Note: In the case of long duration training or project work, where final examination is not possible before the Term ends, a certificate by the course coordinator that the student's progress is satisfactory will be acceptable.

15.3 The student who has been given category NT may appeal to the Appeal Committee giving full reasons for his default. The decision of the Committee in all such cases will be final.

15.4 The student who is given NT category will not be permitted to appear in SEE of the concerned course. He will also be given grade FF in that course.

R.PHARM. (PG) 13. GRADES IN EXAMINATIONS

13.1 CE and LPW EXAMINATIONS

Grades for the CE and LPW examinations will be given on the basis of the percentage marks obtained by the student in the respective examinations.

Table 2(a) shall be referred for converting percentage marks into corresponding Grades (G) for all examinations except CE, and Table 2 (b) for CE.

Table 2 (a)
All examinations except CE

% marks	Grade(G
90 and above	A+
80-89	A
70-79	B+
60-69	B
50-59	C+
Less than 50	IF

Table 2 (b)
for CE

% marks	Grade(G
90 and above	A+
80-89	A
70-79	B+
60-69	B
50-59	C+
45-49	C

13.2 GRADE IN SEE

In the normal course, a student (IR, RPR) and category GT will appear for SEE after his CE and LPW examination, in the same semester. Grade for the performance in SEE will be given on the basis of the percentage marks obtained by the student. Table 2(a) shall be referred to for converting percentage marks into corresponding grades (G) except that for categories - (i) and (ii) given below, grade IF will be given:

Performance	Grade
(i) Fail	IF
(ii) Absence	IF

Notwithstanding anything contained in terms of giving 'IF' grade as shown in (ii) in the table above, the Director of Institute will scrutinize the genuineness about remaining absence in Semester End Examination through Appeal Committee and if the Director, after said scrutiny, decides to show 'Ab' instead 'IF' in (ii) of above table then in the grade sheet, instead of 'IF', 'Ab(S)' shall be mentioned in such cases only.

13.3 GRADE IF IN SEE

The student who obtains grade IF in SEE will be allowed to appear in three consecutively available subsequent SEE of the concerned course. The criteria for giving grades in these three attempts will be the same as given in R. 13.2. However, grade IF in the final attempt will be converted into grade FF.

13.4 COURSE GRADE

Course grade will be given only when the student passes all component examinations. For CE Conditional Pass grade will be allowed in case of Graced Passing. (R-15.2)

Marks of SEE/SPE, CE and LPW (as applicable) examinations shall first be aggregated on the basis of the component / *inter se* weights given in the Teaching Scheme. After the aggregate marks of the entire group are so calculated, the performance of each student in the course as a whole will be assigned a grade based on his aggregate percentage viewed in relation to the overall performance of the group.

In giving relative grades, the number and designation of various grades (G) shall be kept the same as shown in Table 2(a). The course coordinator will decide the cut off percentages of relative grading subject to the guidelines prescribed by the Academic Council.

The Transcript will show only the Course Grade and not the Component Grades.

13.5 The provisions of R. 13.4 are subject to the maximum permissible duration to pass courses of first two semesters and the entire Programme given in R.17.

R.PHARM. (PG) 14. INTERPRETATION OF GRADES

(a) Grade A+ should be given with great care and discretion. Normally it should be reserved for a very distinguished performance, with respect to both marks and quality of output.

(b) Grade C+ is the minimum for passing. A student getting grade C in CE can improve his performance (at his option) by repeating [1]CE in subsequent semester. Better of the grades obtained in the two examinations will be considered.

(c) Grade FF –
  (i) If this grade is given because of NT, the student will have to seek RS registration respectively for repeat study of the course.

  (ii) If the grade FF is given due to failure in the final admissible attempt in SEE, the student will have to seek RS registration for repeat study.

(d) Grade IF - This is an interim fail grade given in CE, LPW and SEE/SPE as under:

Performance	Grade
Fail in CE	IF(C)
Fail in LPW	IF(L)
Fail in SEE/SPE	IF(S)
Fail in Overall Course	IF(O)

Note: If a student getting IF (O) in a course, then he/she can improve his/her performance by repeating CE (all components of CE) of the course in the subsequent semester depending upon his/her choice. In such case, he/she will also reappear in SEE.

R.PHARM. (PG) 15. PASSING STANDARDS

15.1 PASSING A COMPONENT

The standards of passing a component / course / Programme are given below.
(Min C+ means grade C+ or a better grade)

COMPONENT	--	Min C in each component examination i.e. CE, LPW and SEE/SPE
CE	--	Min. C+ (in case of grade C refer regulation for Gracing)
LPW	--	Min C+
SEE/SPE	--	Min C+
COURSE	--	Min C+

15.2 GRACING -- A student not satisfying condition given in R 15.1 for passing a given course will be deemed to have been "Graced for passing" the course if the student fulfills the following two conditions:

(i)Grade C in CE

(ii)Min C + in SEE, CE and LPW (as applicable) and Min C+ in the course

A student will be allowed a total of only two Gracing in the entire programme.

No special mention about gracing will be made in the transcript.

15.3 PROGRAMME -- Total credits of all credit courses of the Programme with CPI min 6.0**.**

15.4 FAILURE -- Student not satisfying these criteria of Passing / Gracing / will be considered as having Failed in the Examination / Component / Course / Programme.

15.5 The student who has once passed an examination will not be allowed to appear at it again.

15.6 Grades/marks obtained by the student in examinations passed by him will be carried forward as necessary.

R.PHARM. (PG) 16. PERFORMANCE LEVELS

16.1 INDICES

The performance level of the student in credit courses at different stages of his study is given by the following indices. All index values will be rounded off to the second place of decimal.

PIC -- Performance index for the course

PPI -- Progressive Performance Index

SPI -- Semester Performance index

CPI -- Cumulative Performance index

PIC -- Equivalent grade point (g) corresponding to the course grade (R. 10 and 13.4)

PPI -- (Up to any stage under consideration)

PPI = (i1 c1 + i2 c2 + i3 c3 .....) / (sum of credits of all courses registered up to that stage)

Where:

i1, i2, i3…….. are PIC values of CREDIT COURSES passed and

c1, c2, c3….. are the credit values of the respective courses.

SPI -- This index is similar to PPI except that the stage to be considered is the end of a semester.

CPI -- This index refers to the entire programme. It is calculated when the student passes the programme. The method of calculation is the same as for PPI or SPI but the summation is for the courses of all semesters of the programme.

16.2 CLASS AND PERCENTAGE (%) MARKS

In case an equivalence between CPI values and Class / % marks is desired, the same can be obtained as given below:

% marks = (CPI – 0.5)* 10

CLASS

CPI Value	**Equivalent Class**
6.00 to 6.49	Second
6.50 to 7.49	First
7.50 and above	First- with distinction

R.PHARM. (PG) 17.CANCELLATION OF ADMISSION

The admission in the Programme of the following categories of students is liable to be cancelled.

17.1

(i) Failure to earn credits for all courses of semester I within two years of admission to the Programme.

(ii) Failure to earn credits for all courses of semester II within two and a half years of admission to the Programme.

(iii) Failure to earn requisite credits and CPI minimum 6.00 to pass the Programme within three years of admission to the Programme.

The student, whose admission is so cancelled, can appeal to the Appeal Committee. The Committee may grant an extension only upto one additional semester for one of the categories falling under 17.1 (i), (ii) or (iii) for clearing the courses in deserving cases, provided the student gives a viable assurance to make up the shortfall within that period.

Notwithstanding anything contained above, the President may consider the cases of such students falling under category (i), (ii) & (iii), if the student has cleared all the courses and have earned the requisite number of credits except one course, on an appeal filed. The President will consider such appeal on the recommendation of the appeal committee prescribed under the regulations for the purpose and after considering the genuineness of the case may give one additional attempt to the student concerned to clear the remaining course.

17.2 The student who satisfies R. 17.1 (i) and (ii) but who is unable to satisfy R.17.1 (iii) only because of delay in completing the Thesis work may apply, giving full reasons, to the HOD for an extension to submit his Thesis. The HOD may recommend to the Appeal Committee to grant an extension of up to two years in addition to the limit specified R. 17.1 (iii). The decision of the Appeal Committee in the case will be final.

17.3 If a student avails of the benefit of R. 17.2, and he passes the Programme, his Grade for passing the Programme will be pegged at C+ and CPI at 6.0.

R.PHARM. (PG) 18. EXAMINERS

All continuous assessments will be carried out by the faculty concerned. All other assessments / examinations will be carried out by a panel of at least two examiners. The extent of associating external experts with the examinations, selection and appointment of all examiners will be decided by the Dean in consultation with a committee appointed for this purpose.

R.PHARM. (PG) 19. SUMMER SEMESTER COURSES AND EXAMINATIONS

19.1 The Institute may offer the following two types of courses in the Summer Semester. No separate registration is necessary to attend a course in summer semester.

(i) For students with RER registration -- Courses in which only the LECT component will be taught.
(ii) For students with RPR registration -- Courses in which all applicable components will be taught.

A course will be offered if a minimum number of eight students apply for enrolment. The Director is empowered to relax this condition as he deems fit.

19.2 For type (i) courses, the Summer Semester end examination will be considered as SEE as applicable to each student. If the student gets passing grade in the examination, he will be given the appropriate grade, otherwise the status of his registration before Summer Semester will remain unchanged.

19.3 For type (ii) courses, all Regulations applicable to IR and RPR registrations will apply. Examinations i.e. CE, LPW and SEE as applicable will be taken. No Block, Supplementary or additional examination will be taken.

If the student passes in the course, he will be given the appropriate grade, otherwise the status of his registration before Summer Semester will remain unchanged.

19.4 The maximum number of enrolments allowed to a student will be as follows:

Only RER -- 3
Only RPR -- 2
RPR + RER -- 1+1

R.PHARM. (PG) 20. SUPPLEMENTARY COURSES

The courses of this category are basically bridge courses to bring students of different universities to a common level in certain areas of basic importance to the Programme.
The Dean of the Faculty of Pharmacy is empowered to decide these courses, their curriculum, teaching and examination schemes, passing standards and such other matters as may be necessary for efficient conduct of the courses.

DISCLAIMER:
Though full care is taken to prepare this regulation, yet, in case of doubt, it is advisable to refer the concerned notification(s) published from time to time.

Section - II

NIRMA UNIVERSITY
INSTITUTE OF PHARMACY
PROGRAMME: MASTER OF PHARMACY IN PHARMACEUTICS

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of *(M. Pharm. - Pharmaceutics)*

Semester I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MPH101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPH102T	Drug Delivery Systems	4	-	-	4	3.0	-	0.60	-	0.40
3	MPH103T	Modern Pharmaceutics	4	-	-	4	3.0	-	0.60	-	0.40
4	MPH104T	Regulatory Affairs	4	-	-	4	3.0	-	0.60	-	0.40
5	MPH105P	Pharmaceutics Practical I	-	12	-	6	-	6.0	-	1.00	-
6	-	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	**-**	**26**					
			35								

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

1

Appendix-A
(Noti. No. NU(-
AC mtg.-174(17)

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm. : Pharmaceutics)
(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPH101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives:

After completion of course student is able to know,

1. Chemicals and Excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Recall the fundamental concepts of different spectroscopic techniques.
2. Understand the basics of immunological assays.
3. Recognize the fundamentals, instrumentation and applications of various chromatographic methods
4. Discuss the instrumentation and application of various spectroscopic techniques
5. Describe various electrophoretic techniques

Syllabus: **Teaching hours: 60 Hours**

UNIT I **11 Hours**

- **UV-Visible spectroscopy:**

  Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

  IR spectroscopy:

  Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

  Spectroflourimetry:

  Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

  Flame emission spectroscopy and Atomic absorption spectroscopy:

  Principle, Instrumentation, Interferences and Applications.

UNIT II **11 Hours**

- **NMR spectroscopy:**
  Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant. Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

UNIT III **11 Hours**

- **Mass Spectroscopy:**
  Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight. Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT IV **11 Hours**

- **Chromatography:**
  Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
  - Paper Chromatoraphy
  - Thin Layer chromatography
  - Ion exchange chromatography
  - Column chromatography
  - Gas chromatography
  - High Performance Liquid chromatography
  - Affinity chromatography

UNIT V **16 Hours**

- **Electrophoresis:**
  Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
  - Paper electrophoresis
  - Gel electrophoresis
  - Capillary electrophoresis
  - Zone electrophoresis
  - Moving boundary electrophoresis
  - Iso electric focusing

  X ray Crystallography:
  Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

- **Immunological assays:**
  RIA (Radio immune assay), ELISA, Bioluminescence assays.

Suggested Readings^: (Latest edition)

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., & Bryce, D. L. Spectrometric Identification of Organic Compounds. Johnwiley & sons.
2. Skoog, D. A. H., James, F., & Nieman, T. A. Principles of Instrumental Analysis. Eastern press.
3. Hobart, W. H., Merritt LL, Dean John. A., Instrumental Methods of Analysis. CBS publishers.
4. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.

5. Kemp, W. Organic Spectroscopy. ELBS.
6. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. CBS Publishers.
7. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPH 102T**
Course Title	**Drug Delivery Systems**

Scope:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives:

Upon completion of the course, student should be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of delivering systems
3. The formulation and evaluation of Novel drug delivery systems.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Understand the concepts and approaches of sustained/controlled and novel drug delivery systems.
2. Demonstrate techniques for formulation development of novel drug delivery
3. Discuss various approaches for site specific drug delivery systems.
4. Describe types of drug targeting and its applications.
5. Evaluate novel oral, topical and parenteral drug delivery systems.

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **10 Hours**

- **Sustained Release (SR) and Controlled Release (CR) formulation:**
  Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

UNIT – II **10 Hours**

- **Rate Controlled Drug Delivery Systems:**

Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, PH activated , Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

UNIT – III **10 Hours**

- **Gastro-Retentive Drug Delivery Systems:**
  Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

UNIT – IV **16 Hours**

- **Occular Drug Delivery Systems:**
  Barriers of drug permeation, Methods to overcome barriers.
- **Trans Dermal Drug Delivery Systems:**
  Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

UNIT – V **14 Hours**

- **Protein and Peptide Delivery:**
  Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.
- **Vaccine delivery systems:**
  Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Suggested Readings^: (Latest Edition)

1. Chien, Y W. Novel Drug Delivery Systems, New York: Marcel Dekker, Inc.
2. Robinson, J. R., Lee V. H. L. Controlled Drug Delivery Systems, New York: Marcel Dekker, Inc.
3. Edith Mathiowitz, Encyclopedia of controlled delivery, New York: Wiley Interscience Publication, John Wiley and Sons, Inc.
4. Jain, N.K. Controlled and Novel Drug Delivery, New Delhi: CBS Publishers & Distributors.
5. Vyas, S. P. and Khar, R. K. Controlled Drug Delivery - concepts and advances, New Delhi: Vallabh Prakashan.

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPH 103T**
Course Title	**Modern Pharmaceutics**

Scope:

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives:

Upon completion of the course, student should be able to understand

1. The elements of preformulation studies.
2. The Active Pharmaceutical Ingredients and Generic drug Product development
3. Industrial Management and GMP Considerations.
4. Optimization Techniques & Pilot Plant Scale Up Techniques
5. Stability Testing, sterilization process & packaging of dosage forms.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Identify key preformulation parameters for various dosage forms
2. Recognize the importance of optimization techniques and its selection
3. Explain types, protocol and process of validation
4. Correlate GMP with pharmaceutical production including pilot scale up
5. Estimate diffusion and dissolution parameters for drug release
6. Prepare stability, sterilization and packaging protocol of various dosage forms

Syllabus: **Teaching hours: 60 Hours**

UNIT I **10 Hours**

- **Preformation Concepts:** Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability, Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

UNIT II **10 Hours**

- **Optimization techniques in Pharmaceutical Formulation**: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

UNIT III **10 Hours**

- **Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & PQ of facilities

UNIT IV **10 Hours**

- **eGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

UNIT V **20 Hours**

- **Compression and compaction**: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.
- **Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f2 and f1, Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test , Anova test.

Suggested Readings^: (Latest Edition)

1. Leon Lachmann, & Herbert, A.L. The Theory and Practice of Industrial Pharmacy. New Delhi: CBS Publishers & Distributors Pvt. Ltd.
2. Lieberman, H.A., Leon, Lachmann, Schwartz, J. B. Pharmaceutical dosage forms: Tablets Vol. 1-3, New York: Marcel Dekker
3. Lieberman, H.A., Leon, Lachmann, Schwartz, J. B. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2, New York: Marcel Dekker
4. Lieberman, H.A., Leon, Lachmann, Schwartz, J. B. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2, New York: Marcel Dekker
5. Gilbert, S.B. and Rhodes, C.T. Modern Pharmaceutics, New York: Marcel Dekker
6. Remington, J. P., & Gennaro, A. R. Remington: The Science and Practice of Pharmacy. Lippincott Williams.
7. Bean, H.S. and Beckett, A.H. Advances in Pharmaceutical Sciences, London: Academic Press
8. Sinko, Martyns Physical Pharmacy and Pharmaccutical Sciences, Lippincott Williams and Walkins.
9. Bentley, A.O., & Rawlins, E.A. Bentley's Text Book of Pharmaceutics. USA: Elsevier Health Sciences.
10. Sidney, H. W. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, New York: Marcel Dekker.
11. Organization of Pharmaceutical producers of India. Quality Assurance Guide.
12. Kohli, D.P.S. and Shah, D.H. Drug formulation manual, New Delhi: Eastern publishers
13. Sharma, P.P. How to practice GMPs, Agra: Vandhana Publications.
14. Berry, F.R. and Nash, R.A. Pharmaceutical Process Validation, Marcel Dekker
15. Wells, J. J. Pharmaceutical Preformulations, Ellis Horwood Limited
16. Evans J.R., Anderson Sweeney and Williams. Applied production and operations management, south-Western.
17. Swarbrick, J. Encyclopaedia of Pharmaceutical technology, Vol I III, CRC press.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPH 104T**
Course Title	**Regulatory Affairs**

Scope:

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

1. The Concepts of innovator and generic drugs, drug development process
2. The Regulatory guidance's and guidelines for filing and approval process
3. Preparation of Dossiers and their submission to regulatory agencies in different countries
4. Post approval regulatory requirements for actives and drug products
5. Submission of global documents in CTD/ eCTD formats
6. Clinical trials requirements for approvals for conducting clinical trials
7. Pharmacovigilence and process of monitoring in clinical trials.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Understand the drug approval processes for various regulatory agencies
2. Explain various types of documentation in pharmaceutical Industries
3. Understand preparation of Dossiers and their submission including post approval requirements for different countries
4. Describe global submission of IND, NDA and ANDA.
5. Review the requirements for approvals for conducting clinical trials
6. Interpret various regulations for clinical trials and pharmacovigilance

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

- **Documentation in pharmaceutical industry**: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments , CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

UNIT II **12 Hours**

- **Regulatory requirement for product approval**: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

UNIT III **12 Hours**

- **Regulatory requirements of various countries:** CMC, post approval regulatory affairs. Regulation for combination products and medical devices CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q,S E,M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

UNIT IV **12 Hours**

- **Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

UNIT V **12 Hours**

- **Clinical trials: D**eveloping clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

Suggested Readings^: (Latest Edition)

1. Leon Shargel and IsaderKaufer, Generic Drug Product Development, Solid Oral Dosage forms, Marcel Dekker series.
2. Berry, I. R. and Robert, P. M. The Pharmaceutical Regulatory Process, Drugs and the Pharmaceutical Sciences, Informa Health care Publishers.
3. Richard, A. G., New Drug Approval Process: Accelerating Global Registrations, Drugs and the Pharmaceutical Sciences, Informa Healthcare
4. Sandy Weinberg. Guidebook for drug regulatory submissions, Wiley & Sons.Inc.
5. Douglas J. P., David Mantus. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics Informa Healthcare
6. Fay A. R. and Rodney K. A. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance, John Wiley & Sons.
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

Revised Syllabus

(M. Pharm. : Pharmaceutics)

(Semester – I)

L	T	P	C
-	-	12	6

Course Code	MPH 105P
Course Title	Pharmaceutics Practical I

PRACTICALS 180 Hours

Unit 1: 45 hours

Sr. No	Title	Hours
1	To perform In-vitro dissolution profile of CR/ SR marketed formulation.	6
2	Formulation and evaluation of sustained release matrix tablets / microspheres using a suitable optimization technique	6
3	Formulation and evaluation osmotically controlled DDS	9
4	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS	9
5	Formulation and evaluation of Mucoadhesive tablets.	6
6	Formulation and evaluation of transdermal patches and in-situ ocular gel	9

Unit 2: 45 hours

Sr. No	Title	Hours
1	To carry out preformulation studies of tablets.	6
2	To study the effect of compressional force on tablets disintegration time.	3
3	To study Micromeritic properties of powders and granulation.	3

4	To study the effect of particle size on dissolution of a tablet.	6
5	To study the effect of binders on dissolution of a tablet.	6
6	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.	6
7	To prepare GMP protocols for manufacturing and packaging of pharmaceuticals.	3
8	To improve solubility of poorly soluble drug by solid dispersion technique using Screening Design.	6
9	To perform validation of tablet machine.	3
10	To study the factors affecting microemulsion.	3

Unit 3: 45 hours

Sr. No	Title	Hours
1	Prepare batch manufacturing record / Batch Packaging record sustained release tablet.	6
2	Prepare an outline of DMF for API manufacturing for drug products to be sold in USA.	6
3	Compile all information of RLD/RS for Doxorubicin liposomes for ANDA filling.	6
4	Preparation of Module 3 as per e-CTD for filing NDA.	6
5	Preparation of IMPD and IB documents for EU filing.	6
6	Filling of form 356h and 510K for anticancer drug and stent respectively.	3
7	Outline the process of drug product approval in India as per CDSCO.	3
8	Prepare protocol for conduct of BA-BE studies as per regulatory guideline.	6
9	Requirements of clinical trial process as per HIPAA	3

Unit 4 : 45 Hours

Sr. No	Title	Hours
1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer	6
2	Simultaneous estimation of single and multi component containing formulations by UV spectrophotometry	12
3	Experiments based on HPLC **(a) Analysis of API using HPLC**	12

	(b) Estimation of drug in various formulations	
4	Experiments based on Gas Chromatography **(a) Analysis of volatile components using GC.** **(b) Analysis of given formulation for presence of residual solvents using GC**	6
5	Estimation of riboflavin/quinine sulphate by fluorimetry	3
6	Estimation of sodium/potassium by flame photometry	3
7	Estimation of impurities in drug and excipients using TLC and HPTLC	3

NIRMA UNIVERSITY
Institute of Pharmacy

Teaching & Examination Scheme *(M. Pharm - Pharmaceutics)*

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPH201T	Molecular Pharmaceutics (Nano Tech & Targeted DDS)	4	-	-	4	3.0	-	0.60	-	0.40
2	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	-	-	4	3.0	-	0.60	-	0.40
3	MPH203T	Computer Aided Drug Delivery System	4	-	-	4	3.0	-	0.60	-	0.40
4	MPH204T	Cosmetics and Cosmeceuticals	4	-	-	4	3.0	-	0.60	-	0.40
5	MPH205P	Pharmaceutics Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MPH206S	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**		**26**					
			35								

L: *Lectures*, P/T: *Practicals/Tutorial*, C: *Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

w.e.f. academic year 2017-2018 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Pharmaceutics)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPH201T**
Course Title	**Molecular Pharmaceutics (Nano Tech & Targeted DDS)**

Scope:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives:

After completion of course student is able to know -

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS.
3. The formulation and evaluation of novel drug delivery systems.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Understand the concepts of targeted and nucleic acid based drug delivery systems.
2. Compare various approaches for development of targeted drug delivery systems.
3. Explain types, manufacturing techniques and applications of microparticulate, nanoparticulate and vesicular drug delivery systems.
4. Discuss various approaches for pulmonary drug delivery systems.
5. Analyze various nano and targeted drug delivery systems.

Syllabus: **Teaching Hours: 60 Hours**

UNIT I **12 Hours**

Targeted Drug Delivery Systems:

Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

UNIT II **12 Hours**

Targeting Methods:

Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

UNIT III **12 Hours**

Micro Capsules / Micro Spheres:

Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

UNIT IV **12 Hours**

Pulmonary Drug Delivery Systems:

Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT V **12 Hours**

Nucleic acid based therapeutic delivery system:

Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Suggested Readings^: (Latest edition)

1. Chien Y W., *Novel Drug Delivery Systems*, Marcel Dekker, Inc., New York.
2. Vyas S. P. and Khar R. K., *Controlled Drug Delivery - concepts and advances*, Vallabh Prakashan, New Delhi.
3. Jain N. K., *Controlled and Novel Drug Delivery*, CBS Publishers & Distributors, New Delhi.
4. Narang A.S., Mahato R.I.. *Targeted Delivery of Small & Macromolecular Drugs*, CRC Press, Boca Raton.
5. Hillery A. M., Lloyd A. W., Swarbrick J., *Drug Delivery and Targeting: For Pharmacists and Pharmaceutical Scientists*, Taylor & Francis, Inc., New York.
6. Jorgensen L., Nielsen H. M., *Delivery Techniques for Biopharmaceuticals*, Wiley Interscience, UK.
7. Robinson J. R., Lee V. H. L., *Controlled drug delivery: Fundamentals and applications*. New York: Informa Health Care.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm - Pharmaceutics)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPH202T**
Course Title	**Advanced Biopharmaceutics & Pharmacokinetics**

Scope:

This course is designed to impart knowledge and skills necessary for dose calculations, dose

adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives:

After completion of course student is able to know-

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand concept of drug absorption in human body.
2. Correlate dissolution data with its pharmacokinetic data.
3. Derive the pharmacokinetic parameters along with its applications.
4. Estimate pharmacokinetic parameters with its interpretation.
5. Explain development of BA-BE protocol as per various regulatory guidelines.
6. Apply concepts of pharmacokinetics in clinical situations.

Syllabus:

Teaching Hours: 60 Hours

UNIT I **12 Hours**

Drug Absorption From The Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH–partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

UNIT II **12 Hours**

Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:

Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products. In Vitro–In Vivo Correlation,

Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.

UNIT III **12 Hours**

Pharmacokinetics:

Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max}. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

UNIT IV **12 Hours**

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process. Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

UNIT V **12 Hours**

Application of Pharmacokinetics:

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

Suggested Readings^: (Latest edition)

1. Gibaldi Milo. *Biopharmaceutics and Clinical Pharmacokinetics*, Philadelphia, Lea and Febiger.
2. Brahmankar D. M., Jaiswal S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise*, Delhi, Vallabh Prakashan.
3. Shargel L., Andrew Yu, Susanna Wu-Pong, *Applied Biopharmaceutics and Pharmacokinetics*, McGraw Hill Professional, USA.
4. Rani S., Hiremath, R. *Textbook of Biopharmaceutics and Pharmacokinetics*, Prism Book.
5. Gibaldi M., Perrier D. *Pharmacokinetics*, New York, Marcel Dekker Inc.
6. Swarbrick. J, *Current Concepts in Pharmaceutical Sciences: Biopharmaceutics*. Philadelphia, Leaand Febiger.
7. Rowland M., Tozer T. *Clinical Pharmacokinetics, Concepts and Applications*, Philadelphia, Leaand Febiger.
8. Abdou H. M, *Dissolution, Bioavailability and Bioequivalence*, Pennsylvania, Mack Publishing Company.
9. Notari R. E. *Biopharmaceutics and Clinical Pharmacokinetics, An Introduction*, New York, Marcel Dekker Inc,
10. Wagner J. G., Pemarowski M. *Biopharmaceutics and Relevant Pharmacokinetics*, Hamilton, Illinois, Drug Intelligence Publications.
11. Swarbrick J., Boylan J. G. *Encyclopedia of Pharmaceutical Technology*, New York, Marcel Dekker Inc,

12. Jambhekar S. S., Breen P J. *Basic Pharmacokinetics*, Pharmaceutical Press, RPS Publishing.
13. Avdeef A. *Absorption and Drug Development- Solubility, Permeability, and Charge State.* John Wiley & Sons, Inc

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^ this is not an exhaustive list

(M. Pharm - Pharmaceutics)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPH203T**
Course Title	**Computer Aided Drug Delivery System**

Scope:

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives:

After completion of course student is able to know -

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics(CFD)

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand applications of computers in pharmaceutical research and development.
2. Discuss QbD guidelines with its implications in pharmaceutical industry.
3. Relate drug delivery with Artificial intelligence (AI), Robotics and Computational fluid dynamics.
4. Describe significance of computational modeling of drug disposition.
5. Apply optimization techniques in development of pharmaceutical formulation.
6. Interpret computer generated market analysis and clinical development data.

Syllabus: **Teaching Hours: 60 Hours**

UNIT I **12 Hours**

Computers in Pharmaceutical Research and Development:

A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter ,Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

Quality-by-Design In Pharmaceutical Development:

Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

UNIT II **12 Hours**

Computational Modeling of Drug Disposition:

Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

UNIT III **12 Hours**

Computer-aided formulation development:

Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

UNIT IV **12 Hours**

Computer-aided biopharmaceutical characterization:

Gastrointestinal absorption simulation Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations

Computer Simulations in Pharmacokinetics and Pharmacodynamics:

Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

Computers in Clinical Development:

Clinical Data Collection and Management, Regulation of Computer Systems

UNIT V **12 Hours**

Artificial Intelligence (AI), Robotics and Computational fluid dynamics:

General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Suggested Readings^: (Latest edition)

1. Ekins, S. *Computer Applications in Pharmaceutical Research and Development.* John Wiley & Sons, UK.
2. Djuris, J. *Computer-Aided Applications in Pharmaceutical Technology.* Woodhead Publishing.
3. Swarbrick, J. Boylan, J.G. *Encyclopedia of Pharmaceutical Technology (Volume 20).* New York, Marcel Dekker Inc, USA.

4. Nag, A. Dey, B. *Computer-Aided Drug Design and Delivery Systems*. The McGraw-Hill Companies, Inc. NewYork.
5. Reklaitis G, Seymour C, García-Munoz S. *Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture*. Wiley-Blackwell, UK.

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^ this is not an exhaustive list

(M. Pharm - Pharmaceutics)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPH204T**
Course Title	**Cosmetics and Cosmeceuticals**

Scope:
This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives:
Upon completion of the course, the students shall be able to know -
1. Key ingredients used in cosmetics and cosmeceuticals.
2. Key building blocks for various formulations.
3. Current technologies in the market.
4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals.
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -
1. Understand regulatory requirements of cosmeceuticals.
2. Discuss safety, stability, and efficacy aspects of cosmetic products.
3. Identify key ingredients used in cosmetics and cosmeceuticals.
4. Explain current technologies for cosmetic manufacturing.
5. Design and develop cosmetics and cosmeceuticals.

Syllabus: **Teaching Hours: 60 Hours**

UNIT I **12 Hours**

Cosmetics – Regulatory:
Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

UNIT II **12 Hours**

Cosmetics - Biological aspects:

Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III **12 Hours**

Formulation Building blocks:

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars.

Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV **12 Hours**

Design of cosmeceutical products:

Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT V **12 Hours**

Herbal Cosmetics:

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

Suggested Readings^: (Latest Edition)

1. Rieger, M. *Harry's Cosmeticology: volume 2*. Chemical Publishing Company.
2. Saraf, S., & Saraf, S. *Cosmetics a practical manual*. PharmaMed Press, Hyderabad.
3. Butler, H. *Poucher's perfumes, cosmetics, and soaps*. Dordrecht: Kluwer Academic.
4. Williams, D. F., & Schmitt, W. H. *Chemistry and Technology of the Cosmetics and Toiletries Industry*. Dordrecht: Springer Netherlands.
5. Barel, A. O., Paye, M., & Maibach, H. I. *Handbook of cosmetic science and technology*. New York: Marcel Dekker.
6. *CTFA membership directory*. CTFA, Washington, USA.
7. *Khar, R.* K. *Cosmetic Technology*. Birla Publications, Delhi.
8. *Sharma, P.P. Cosmetic Formulations Manufacturing and Quality Control.* Vandana Publication, Delhi.
9. Sampath K. *A Concise Book of Cosmetic*. Birla Publications Pvt. Ltd., Delhi.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm - Pharmaceutics)
(Semester – II)

L	T	P	C
-	-	12	6

Course Code	**MPH 205P**
Course Title	**Pharmaceutics Practical II**

PRACTICALS **180 Hours**

1. To study the effect of temperature change , non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands .
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

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Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M.Pharm. - Pharmaceutics)

Semester - III

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MPH302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MPH303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MPH304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPH401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MPH402P	Research work and Colloquium		31	-	16	-	1.0		1.0	-
3	MPH403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

Appendix - A
Noti. No. - NU - 31
Acmt - 20.04.18

w.e.f. academic year 2018-2019 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm)
(Semester - III)

L	T	P	C
4	-	-	4

Course Code	MRM301T
Course Title	Research Methodology & Biostatistics

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. List various types of research and significance of review of literature
2. Describe the parametric and non- parametric tests related to biostatistics
3. Discuss various types of medical research
4. Explain CPCSEA guidelines for laboratory animal facility
5. Express the role of declaration of Helsinki

Syllabus: **Teaching hours: 60 Hours**

UNIT I **15 Hours**

General Research Methodology: Research, objective, protocol design, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding and related labelling techniques, conduct, monitoring, analysis and interpretation, reporting and record keeping, Scientific writing.

UNIT II **20 Hours**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values, application based case studies.

UNIT III **10 Hours**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT IV **05 Hours**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals, Import of animals.

UNIT V **10 Hours**

General Guidelines of clinical research, ICH E9 guidelines, Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Suggested Readings^: (Latest Edition)

1. Best, J.W., Kahn, J.V., *Research In Education*. New Delhi, Prentice Hall of India Pvt. Ltd.
2. Halton, M., *Presentation Skills*. Indian Society for Institute Education
3. Mcfarlane, G., *A Practical Introduction to Copyright*. McGraw Hill
4. Davis, R.M., *Thesis Projects in Science and Engineering*. St. Martin's Press.
5. Anderson, J., *Thesis and Assignment Writing*. John Wiley & Sons.

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NIRMA UNIVERSITY
INSTITUTE OF PHARMACY
PROGRAMME: MASTER OF PHARMACY IN REGULATORY AFFAIRS

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of *(M.Pharm - Regulatory Affairs)*

Semester - I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRA101T	Good Regulatory Practices	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA102T	Documentation and Regulatory Writing	4	-	-	4	3.0	-	0.60	-	0.40
3	MRA103T	Clinical Research Regulations	4	-	-	4	3.0	-	0.60	-	0.40
4	MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	-	-	4	3.0	-	0.60	-	0.40
5	MRA105P	Regulatory Affairs Practical I	-	12	-	6	-	6.0	-	1.00	-
6		Seminar/Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	**-**	**26**	-	-	-	-	-
			35								

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

NIRMA UNIVERSITY
Institute of Pharmacy

(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MRA101T**
Course Title	**Good Regulatory Practices**

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives

At completion of this course it is expected that students will be able to understand,

1. The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
2. Prepare and implement the check lists and SOPs for various Good Regulatory Practices
3. Implement Good Regulatory Practices in the Healthcare and related Industries
4. Prepare for the readiness and conduct of audits and inspections.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to

1. Understand the concepts of cGMP and GLP
2. Describe the guidance documents for medical device and IVDs
3. Discuss principles and requirements of GALP
4. Review supply chain integrity in GDP
5. Utilize the various elements of QMS
6. Prepare SOP for equipments and processes

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

UNIT – 2 **12 Hours**

Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards

UNIT – III **12 Hours**

Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

UNIT – IV **12 Hours**

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

UNIT – V **12 Hours**

Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

Suggested Readings^: (Latest edition)

1. Weinberg, S. Good Laboratory Practice Regulations. Informa Healthcare.
2. Robinson, D. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by John Sharp. CRC Press.
3. Bliesner, D. M. Establishing a CGMP Laboratory Audit System: A Practical Guide. John Wiley & Sons.
4. Sharma, P. P. How to Practice GLP Good Laboratory Practice. Vandana Publications.
5. Singer, D. C., Stefan, R. I., & Van Staden, J. F. Laboratory Auditing for Quality and Regulatory Compliance. Taylor & Francis.
6. Drugs & Cosmetics Act, Rules & Amendments.

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^ this is not an exhaustive list

(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MRA102T**
Course Title	**Documentation and Regulatory Writing**

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

Upon completion of the course the student shall be able to,

1. Know the various documents pertaining to drugs in pharmaceutical industry
2. Understand the basics of regulatory compilation
3. Create and assemble the regulation submission as per the requirements of agencies
4. Follow up the submissions and post approval document requirements

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. List the different types of documents required for drug product management
2. Understand the concept, content and format of CTD and eCTD submission
3. Describe various types of audits and audit strategies for manufacturing facilities
4. Explain the inspection process of pharmaceutical manufacturing practices along with CAPA
5. Express life cycle management of different types of pharmaceutical dosage form

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

UNIT – II **12 Hours**

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

UNIT – III **12 Hours**

Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

UNIT – IV **12 Hours**

Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

UNIT – V **12 Hours**

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

Suggested Readings^: (Latest edition)

1. Ginsbury, K., & Bismuth, G. Compliance Auditing for Pharmaceutical Manufacturers: A Practical Guide to In-Depth Systems Auditing. CRC Press.
2. Gad, S. C. (Ed.). Pharmaceutical manufacturing handbook: regulations and quality (Vol. 6). John Wiley & Sons.
3. Baird, R. M., Hodges, N. A., & Denyer, S. P. (Eds.). Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices. CRC Press.
4. Singer, D. C., Stefan, R. I., & Van Staden, J. F. Laboratory Auditing for Quality and Regulatory Compliance. Taylor & Francis.
5. Endres, A. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results. John Wiley & Sons.
6. Antony, J., & Preece, D. (Eds.). Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases. Routledge.
7. Lawler, E. E., Mohrman, S. A., & Benson, G. Organizing For High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO report. Jossey-Bass.
8. Fairfield-Sonn, J. W. Corporate Culture and the Quality Organization. Greenwood Publishing Group.
9. Avery, C., & Zabel, D. The Quality Management Sourcebook: An International Guide to Materials and Resources. Routledge.
10. Tague,N. The Quality Toolbox. ASQ Publications
11. Joseph, M., Feo, J. Juran's Quality Handbook. ASQ Publications.
12. Okes, D. Root Cause Analysis: The Core of Problem Solving and Corrective Action-Chapter 1.ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MRA103T**
Course Title	**Clinical Research Regulations**

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

1. History, origin and ethics of clinical and biomedical research and evaluation
2. Clinical drug, medical device development process and different types and phases of clinical trials
3. Regulatory requirements and guidance for conduct of clinical trials and research

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Understand different phases of clinical trials for drug development process
2. Describe the importance of ethics and documentation for clinical trials
3. Differentiate clinical research regulations for drug products filing in India, USA and Europe
4. Discuss different aspects of good clinical practices as per regulatory guidelines.
5. Prepare different modules for dossier filing in USA and Europe

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Clinical Drug Development Process

- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies

Key Concepts of Medical Device Clinical Evaluation

Key concepts of Clinical Investigation

UNIT – II **12 Hours**

Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials

- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

UNIT – III **12 Hours**

Regulations governing Clinical Trials

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

UNIT – IV **12 Hours**

Clinical Research Related Guidelines

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population
- General biostatics principle applied in clinical research

UNIT – V **12 Hours**

USA & EU Guidance

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions
- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch

- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use
- EU MDD with respect to clinical research
- ISO 14155

Suggested Readings^: (Latest edition)

1. Rozovsky, F. A., & Adams, R. K. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance.
2. Barnes, M., Kulynych, J. HIPAA and Human Subjects Research: A Question and Answer.
3. Gallin, J. I., & Ognibene, F. P. (Eds.). Principles and Practice of Clinical Research. Academic Press.
4. Karlberg, J. P. E., & Speers, M. A. (Eds.). Reviewing Clinical Trials: A Guide for the Ethics Committee. Clinical Trials Centre.
5. Cartwright, A. C., & Matthews, B. R. (Eds.). International Pharmaceutical Product Registration. CRC Press.
6. Guarino, R. New Drug Approval Process. Marcel Dekker Inc.
7. Pisano, D. J., & Mantus, D. FDA Regulatory Affairs. CRC Press.
8. Country Specific Guidelines from Official Websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. Medicines and Healthcare products Regulatory Agency: http://www .mhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

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(M.Pharm. - Regulatory Affairs)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	MRA104T
Course Title	**Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India and Intellectual Property Rights**

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives

Upon the completion of the course the student shall be able to:

1. Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
2. Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Understand the rules and regulations for biologicals, herbals, food and nutraceuticals
2. Describe the regulatory requirements and approval procedures for drugs, cosmetics, medical devices etc.
3. Discuss pharmacopoeial standards and other standards like BIS and ISO
4. Explain regulatory requirements for bioequivalence study
5. Tell IPR issues, patent filing, copyright and trademarks

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):

- Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
- Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

UNIT – II **12 Hours**

Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format and contents of Regulatory dossier filing Clinical trial/ investigations

UNIT – III **12 Hours**

Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards

UNIT – IV **12 Hours**

Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study

Stability requirements: ICH and WHO

Guidelines for Drug testing in animals/Preclinical Studies

Animal testing: Rationale for conducting studies, CPCSEA Guidelines

Ethical guidelines for human participants

ICMR-DBT Guidelines for Stem Cell Research

UNIT – V **12 Hours**

Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

Suggested Readings^: (Latest edition)

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India.
2. Bessen, J., & Meurer, M. J. (2008). Patent failure: How judges, bureaucrats, and lawyers put innovators at risk. Princeton University Press.
3. Chin, R., & Lee, B. Y. (2008). Principles and practice of clinical trial medicine. Elsevier.
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA).
6. ICH E6 Guideline — Good Clinical Practicel by ICH Harmonised Tripartite.
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation).
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO.
10. Guidelines from official website of CDSCO.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

Revised Syllabus

(MPharm. Regulatory Affairs)

Semester - I

L	T	P	C
0	0	12	6

Course Code	**MRA105P**
Course Title	**Regulatory Affairs Practical - I**

Syllabus: **Total Teaching hours: 180**

Unit	Syllabus	Teaching hours
Unit-I		**48**
	1. Preparation of SOP on SOP / Preparation of SOP on document and data control	3
	2. Preparation of checklist for 21CFR part11 compliance	3
	3. Preparation of qualification protocol and validation report for HVAC system	6
	4. Preparation of SOP for data backup and restore	3
	5. Case studies on Establishment Inspection Report for nonclinical laboratory study	6
	6. Case studies (4 Nos.) of each of Good Pharmaceutical Practices like GMP, GLP, GCP and GAMP.	6
	7. Preparation of Analytical reports for Stability and validation	6
	8. Preparation of SOP on drug product recall and returns	3
	9. Preparation of SOP on drug product complaint handling	3
	10. GMP Audit Requirements as per CDSCO	6
	11. Comparison study on legal GDP requirements world wide	3
Unit-II		**63**
	1. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.	6
	2. Protocol preparation for MFR	6
	3. Protocol preparation for BMR	6
	4. Protocol preparation for DR	3
	5. Labeling comparison between brand & generics.	6
	6. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM	6
	7. Preparation of checklist for registration of IND as per ICH CTD format.	3
	8. Preparation of checklist for registration of NDA as per ICH CTD format.	3
	9. Preparation of checklist for registration of ANDA as per ICH CTD format.	3
	10. Case studies on response with scientific rationale to USFDA	6

	Warning Letter	
	11. Preparation of submission checklist of IMPD for EU submission.	3
	12. Comparison study of marketing authorization procedures in EU.	3
	13. Comparative study of DMF system in US, EU and Japan	3
	14. Preparation of regulatory submission using eCTD software	6
Unit-III		**36**
	Preparation of clinical trial protocol for registering trial in India	6
	Registration for conducting BA/ BE studies in India	6
	Import of drugs for research and developmental activities	3
	Preparation of Clinical Trial Application (CTA) for US submission	3
	Preparation of Clinical Trial Application (CTA) for EU submission	3
	Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.	3
	Clinical Trials of Investigational Medicinal Products as per MHRA	3
	Regulatory requirements checklist for conducting clinical trials in India.	3
	Regulatory requirements checklist for conducting clinical trials in Europe.	3
	Regulatory requirements checklist for conducting clinical trials in USA	3
Unit-IV		**33**
	Preparation of Informed consent form	3
	Preparation and submission of IAEC protocol	3
	Ethical Protocol Form for Research Involving Human Subjects	3
	Guidelines and format for Drug testing in animals	3
	Guidelines and format for BA/BE studies	3
	Introduction to CTRI	3
	Monograph preparation of selected dosage forms as per IP Part I	3
	Monograph preparation of selected dosage forms as per IP Part II	3
	Registering for different Intellectual Property Rights in India	6
	Preparation and documentation for Indian Patent application.	3

Suggested Readings/ References: (Latest edition)

1. Weinberg, S. Good Laboratory Practice Regulations. Informa Healthcare.
2. Robinson, D. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by John Sharp. CRC Press.
3. Bliesner, D. M. Establishing a CGMP Laboratory Audit System: A Practical Guide. John Wiley & Sons.
4. Sharma, P. P. How to Practice GLP Good Laboratory Practice. Vandana Publications.
5. Singer, D. C., Stefan, R. I., & Van Staden, J. F. Laboratory Auditing for Quality and Regulatory Compliance. Taylor & Francis.
6. Drugs & Cosmetics Act, Rules & Amendments.
7. Ginsbury, K., & Bismuth, G. Compliance Auditing for Pharmaceutical Manufacturers: A Practical Guide to In-Depth Systems Auditing. CRC Press.
8. Gad, S. C. (Ed.). Pharmaceutical manufacturing handbook: regulations and quality (Vol. 6). John Wiley & Sons.

9. Singer, D. C., Stefan, R. I., & Van Staden, J. F. Laboratory Auditing for Quality and Regulatory Compliance. Taylor & Francis.
10. Okes, D. Root Cause Analysis: The Core of Problem Solving and Corrective Action-Chapter 1.ASQ Publications.
11. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP).
12. Rozovsky, F. A., & Adams, R. K. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance.
13. Barnes, M., Kulynych, J. HIPAA and Human Subjects Research: A Question and Answer.
14. Cartwright, A. C., & Matthews, B. R. (Eds.). International Pharmaceutical Product Registration. CRC Press.
15. Guarino, R. New Drug Approval Process. Marcel Dekker Inc.
16. Pisano, D. J., & Mantus, D. FDA Regulatory Affairs. CRC Press.
17. Country Specific Guidelines from Official Websites.
18. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India.
19. Bessen, J., & Meurer, M. J. (2008). Patent failure: How judges, bureaucrats, and lawyers put innovators at risk. Princeton University Press.
20. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA).
21. ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite.
22. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation).
23. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
24. Guidelines for Import and Manufacture of Medical Devices by CDSCO.
25. Guidelines from official website of CDSCO.

NIRMA UNIVERSITY

Institute of Pharmacy

Teaching & Examination Scheme *(M. Pharm - Regulatory Affairs)*

Semester - II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRA201T	Regulatory Aspscts of Drugs & Cosmetics	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA202T	Regulatory Aspsects of Herbal & Biologicals	4	-	-	4	3.0	-	0.60	-	0.40
3	MRA203T	Regulatory Aspects of Medical Devices	4	-	-	4	3.0	-	0.60	-	0.40
4	MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	-	-	4	3.0	-	0.60	-	0.40
5	MRA205P	Regulatory Affairs Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MRA206S	Seminar/Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	-	**26**	-	-	-	-	-
			35								

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

w.e.f. academic year 2017-2018 and onwards

50

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA201T**
Course Title	**Regulatory Aspects of Drugs and Cosmetics**

Scope:

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know -

1. Process of drug discovery and development and generic product development.
2. Regulatory approval process and registration procedures for API and drug products in US, EU.
3. Cosmetics regulations in regulated and semi-regulated countries.
4. A comparative study of India with other global regulated markets.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the basics of global regulatory requirements.
2. Describe the process of drug discovery, development and generic product development.
3. Explain the guidelines for registration and approval process for API, drug products (including orphan drugs) and cosmetics in US, Canada and EU.
4. Express the organization, legislations, regulations and registration procedures of PMDA.
5. Apply the knowledge of regulatory requirements for emerging market.
6. Compare the regulatory requirement for registration of drugs in brazil, ASEAN, CIS and GCC countries.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

USA & CANADA:

Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.

UNIT II **12 Hours**

European Union & Australia:

Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

UNIT III **12 Hours**

Japan:

Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan.

UNIT IV **12 Hours**

Emerging Market:

Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRII, SADC).

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana).

UNIT V **12 Hours**

Brazil, ASEAN, CIS and GCC Countries:

ASIAN Countries:

Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States):

Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine.

GCC (Gulf Cooperation Council) for Arab states:

Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE.

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

Suggested Readings^: (Latest edition)

1. Shargel, L., & Kanfer, I. *Generic drug product development: solid oral dosage forms*. CRC Press.
2. Ira, Berry, *The Pharmaceutical Regulatory Process*, Marcel Dekker Series, Vol 144.
3. Ira, Berry. & Robert, Martin. *The Pharmaceutical Regulatory Process, Drugs and the pharmaceutical sciences*, Vol.185. Informa Healthcare Publishers.
4. Richard, G. *New Drug Approval Process: Accelerating Global Registrations, Drugs and the Pharmaceutical Sciences*, Vol.190.
5. Weinberg, S. *Guidebook for Drug Regulatory Submissions*. John Wiley & Sons.
6. Ng, R. Drugs: F*rom discovery to approval*. John Wiley & Sons.
7. Mathieu, M. P., Keeney, R., & Milne, C. P. *New drug development: a regulatory overview*. Parexel International Corp.
8. Jeffrey, F., Wayne, Pines & Gary, H. *Pharmaceutical Risk Management.*
9. William, K. *Preparation and Maintenance of the IND Application in eCTD Format.*
10. http://www.pmda.go.jp/english
11. http://www.fda.gov
12. http://portal.anvisa.gov.br/wps/portal/anvisa-ingles
13. http://www.ema.europa.eu
14. Country Specific Guidelines from official websites
15. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
16. Denis, H. *Roadmap to an ASEAN economic community*. ISEAS Publications, Singapore , ISBN981-230-347-2
17. Rodolfo, S. *ASEAN*. ISEAS Publications, Singapore, ISBN 978-981-230-750-7
18. Kobayashi-Hillary, M. *Building a future with BRICS: the next decade for offshoring* (Vol. 4643). Springer Science & Business Media.
19. Kobayashi-Hillary, M. *Outsourcing to India: The offshore advantage*. Springer Science & Business Media.
20. *The world Bank*, Washington, DC, ISBN: 0-8212-5896-0.
21. Abbott, F. M., Dukes, M. N. G., & Dukes, G. *Global pharmaceutical policy: ensuring medicines for tomorrow's world*. Edward Elgar Publishing.
22. Low, L., & Salazar, L. C. *The Gulf Cooperation Council: a rising power and lessons for ASEAN* (No. 12). Institute of Southeast Asian Studies.
23. Bhasin, B. *Doing business in the ASEAN countries*. Business Expert Press.

24. Plummer, M. G., & Yue, C. S. *Realizing the ASEAN economic community: A comprehensive assessment. Institute of Southeast Asian Studies.*

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(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA202T**
Course Title	**Regulatory Aspects of Herbal and Biologicals**

Scope:

This course is designed to impart fundamental knowledge on regulatory requirements, licensing and registration, regulation on labelling of biologics in India, USA and Europe. It prepares the students to learn in detail on regulatory requirements for biologics, vaccines and blood products.

Objectives:

Upon the completion of the course the student shall be able to -

1. Know the regulatory requirements for biologics and vaccines.
2. Understand the regulation for newly developed biologics and biosimilars.
3. Know the pre-clinical and clinical development considerations of biologics.
4. Understand the regulatory requirements of blood and/or its components including blood products and label requirements.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the requirement of similar biologics from development to market authorization in India.
2. Discuss the regulatory requirements for the biosimilars in US and EU.
3. Know preclinical and clinical development of biologics.
4. Apply knowledge of regulatory aspects of vaccines, blood products and biological products in India, US and EU.
5. Compare quality, safety, and legislation for herbal products in India, US and EU.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

India :

Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

UNIT II **12 Hours**

USA:

Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

UNIT III **12 Hours**

European Union:

Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.

UNIT IV **12 Hours**

Vaccine regulations in India, US and European Union:

Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network).

UNIT V **12 Hours**

Herbal Products:

Quality, safety and legislation for herbal products in India, USA and European Union.

Suggested Readings^: (Latest edition)

1. Pisano, D. J., & Mantus, D. S. *FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics*. Taylor & Francis US.
2. Wang, W., & Singh, M. *Biological drug products: development and strategies*. John Wiley & Sons.
3. Singh , M. ,Srivastava, I. *Development of Vaccines: From Discovery to Clinical Testing*. Wiley.
4. www.who.int/biologicals/en

5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India.*
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)
12. www.ayush.gov.in

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^ this is not an exhaustive list

(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA203T**
Course Title	**Regulatory Aspects of Medical Devices**

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know -

1. Basics of medical devices and IVDs, process of development, ethical and quality considerations.
2. Harmonization initiatives for approval and marketing of medical devices and IVDs.
3. Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
4. Clinical evaluation and investigation of medical devices and IVDs.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the definition, classification and principles of medical devices and IVDs.
2. Describe the principle of ethics in clinical investigations of medical devices.

3. Explain the quality system regulations and ISO certification for medical devices.
4. Report regulatory approval process for medical device in US and EU.
5. Apply the knowledge of regulatory approval process for medical device in ASEAN, China and Japan.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Medical Devices:

Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF:

Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

UNIT II **12 Hours**

Ethics:

Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011).

Quality: Quality System Regulations of Medical Devices:

ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device.

UNIT III **12 Hours**

USA:

Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

UNIT IV **12 Hours**

European Union:

Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

UNIT V **12 Hours**

ASEAN, China & Japan:

Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.

IMDRF study groups and guidance documents.

Suggested Readings^: (Latest edition)

1. Pisano, D. J., & Mantus, D. S. *FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics*. Taylor & Francis US.
2. Kahan, J. S. *Medical Device Development: A Regulatory Overvie*.
3. Tobin, J. J., & Walsh, G. *Medical product regulatory affairs: pharmaceuticals, diagnostics, medical devices*. John Wiley & Sons.
4. Medina, C. *Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics*. CRC Press.
5. Country Specific Guidelines from official websites.
6. http://www.pmda.go.jp/english
7. http://www.fda.gov .
8. http://www.ema.europa.eu
9. www.iso.org
10. www.eng.sfda.gov.cn
11. www.asean.org

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^ this is not an exhaustive list

(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MRA204T**
Course Title	**Regulatory Aspects of Food & Nutraceuticals**

Scope:

This course is designed to impart the fundamental knowledge on regulatory requirements, registration and labeling regulations of nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on regulatory aspects for nutraceuticals and food supplements.

Objectives:

Upon completion of the course, the student shall be able to -

1. Know the regulatory requirements for nutraceuticals.
2. Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the terminologies for food and nutraceuticals.

2. Discuss the guidelines and GMPs for nutraceuticals.
3. Explain regulations for food safety and nutraceuticals in India.
4. Report regulations for food safety and nutraceuticals in US.
5. Apply the knowledge of food safety and nutraceuticals in EU.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Nutraceuticals:

Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

UNIT II **12 Hours**

Global Aspects:

WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

UNIT III **12 Hours**

India:

Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

UNIT IV **12 Hours**

USA:

US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S.

UNIT V **12 Hours**

European Union:

European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.
Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

Suggested Readings^: (Latest edition)

1. Hasler, C. M. *Regulation of functional foods and nutraceuticals: a global perspective* (Vol. 5). John Wiley & Sons.
2. Bagchi, D. *Nutraceutical and functional food regulations in the United States and around the world.* Academic press.
3. http://www.who.int/publications/guidelines/nutrition/en/

4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
5. Pathak, Y. V. *Handbook of Nutraceuticals Volume II: Scale-Up. Processing and Automation* (Vol. 2). CRC Press.
6. Fortin, N. D. *Food regulation: law, science, policy, and practice*. John Wiley & Sons.
7. Country Specific Guidelines from official websites
8. www.cdsco.nic.in
9. www.fda.gov
10. www.ema.europa.eu
11. www.who.int
12. www.nsf.org

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(M. Pharm - Regulatory Affairs)
(Semester - II)

L	T	P	C
-	-	12	6

Course Code	MRA205P
Course Title	Regulatory Affairs Practical II

Syllabus: **Teaching hours: 180 Hours**

1. Case studies on change management/ change control deviations and Corrective & Preventive Actions (CAPA).
2. Documentation of raw materials analysis as per official monographs.
3. Preparation of audit checklist for various agencies.
4. Preparation of submission to FDA using eCTD software.
5. Preparation of submission to EMA using eCTD software.
6. Preparation of submission to MHRA using eCTD software.
7. Preparation of Biologics License Applications (BLA).
8. Preparation of documents required for Vaccine Product Approval.
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Preparation of Checklist for Registration of Blood and Blood Products.
11. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization.
12. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization.
13. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization.
14. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization.

15. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization.
16. Checklists for 510k and PMA for US market.
17. Checklist for CE marking for various classes of devices for EU.
18. STED Application for Class III Devices.
19. Audit Checklist for Medical Device Facility.
20. Clinical Investigation Plan for Medical Devices.

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Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M. Pharm - Regulatory Affairs)

Semester - III

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MRA302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MRA303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MRA304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRA401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MRA402P	Research work and Colloquium	-	31	-	16	-	1.0		1.0	-
3	MRA403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

w.e.f. academic year 2018-2019 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm)
(Semester - III)

L	T	P	C
4	-	-	4

Course Code	MRM301T
Course Title	Research Methodology & Biostatistics

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. List various types of research and significance of review of literature
2. Describe the parametric and non- parametric tests related to biostatistics
3. Discuss various types of medical research
4. Explain CPCSEA guidelines for laboratory animal facility
5. Express the role of declaration of Helsinki

Syllabus: **Teaching hours: 60 Hours**

UNIT I **15 Hours**

General Research Methodology: Research, objective, protocol design, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding and related labelling techniques, conduct, monitoring, analysis and interpretation, reporting and record keeping, Scientific writing.

UNIT II **20 Hours**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values, application based case studies.

UNIT III **10 Hours**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT IV **05 Hours**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals, Import of animals.

UNIT V **10 Hours**

General Guidelines of clinical research, ICH E9 guidelines, Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Suggested Readings^: (Latest Edition)

1. Best, J.W., Kahn, J.V., *Research In Education*. New Delhi, Prentice Hall of India Pvt. Ltd.
2. Halton, M., *Presentation Skills*. Indian Society for Institute Education
3. Mcfarlane, G., *A Practical Introduction to Copyright*. McGraw Hill
4. Davis, R.M., *Thesis Projects in Science and Engineering*. St. Martin's Press.
5. Anderson, J., *Thesis and Assignment Writing*. John Wiley & Sons.

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NIRMA UNIVERSITY
INSTITUTE OF PHARMACY
PROGRAMME: MASTER OF PHARMACY IN PHARMACOLOGY

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of *(M. Pharm. - Pharmacology)*

Semester I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MPL101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPL102T	Advanced Pharmacology-I	4	-	-	4	3.0	-	0.60	-	0.40
3	MPL103T	Pharmacological and Toxicological Screening Methods-I	4	-	-	4	3.0	-	0.60	-	0.40
4	MPL104T	Cellular and Molecular Pharmacology	4	-	-	4	3.0	-	0.60	-	0.40
5	MPL105P	Pharmacological Practical I	-	12	-	6	-	6.0	-	1.00	-
6	-	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	-	**26**					
				35							

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

w.e.f. academic year 2017-2018 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M.Pharm. - Pharmacology)
(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPL101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Objectives:

After completion of course student is able to know about –

1. Chemicals and excipients.
2. Analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Recall knowledge of various chemicals and excipients.
2. Understand fundamental theories of various analytical techniques.
3. Apply practical skills of the instruments.
4. Interpret the results of various spectroscopic and chromatographic techniques.
5. Analyze various drugs in single and combination dosage forms using various qualitative and quantitative analysis methods.
6. Predict the structure of a molecule using various spectral data.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **10 Hours**

UV-Visible spectroscopy

Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/Derivative spectroscopy.

IR spectroscopy

Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factor affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

Spectroflourimetry

Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy

Principle, Instrumentation, Interferences and Applications.

UNIT II **10 Hours**

NMR spectroscopy

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

UNIT III **10 Hours**

Mass Spectroscopy

Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **10 Hours**

Chromatography

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drugs from excipients, data interpretation and applications of the following:

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra-High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

UNIT V **10 Hours**

Electrophoresis

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Iso electric focusing

X ray Crystallography:

Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

UNIT VI **10 Hours**

Potentiometry

Principle, working, Ion selective Electrodes and Application of potentiometry.

Thermal Techniques:

Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

Suggested Readings^: (Latest Edition)

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., Bryce, D. L. Spectrometric Identification of Organic Compounds. USA: John Wiley & Sons.
2. Skoog, D. A. H., James, F., & Nieman, T. A. Principles of Instrumental Analysis. Eastern Press.
3. Hobart, W. H., Merritt LL, Dean John. A., Instrumental Methods of Analysis. CBS Publishers.
4. Beckett, A. H., Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry (Vol. 1 & 2). A&C Black.
5. Kemp, W. Organic Spectroscopy. ELBS.
6. Sethi, P.D. Quantitative Analysis of Drugs in Pharmaceutical formulation. New Delhi: CBS Publishers.
7. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.
8. Kalsi, P. S. Spectroscopy of Organic Compounds. Wiley Estern Ltd.
9. Connors, K. A. A Textbook of Pharmaceutical Analysis. USA: John Wiley and Sons.

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(M.Pharm. - Pharmacology)
(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPL102T**
Course Title	**Advanced Pharmacology-I**

Scope:

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved.

Course Objectives:

Upon completion of the course the student shall be able to -

1. Discuss the pathophysiology and pharmacotherapy of certain diseases.
2. Explain the mechanism of drug actions at cellular and molecular level.

3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Recall basic concepts of pharmacokinetics.
2. Describe the fundamental aspects of pharmacodynamics.
3. Discuss principles of neurotransmission.
4. Explain the pathophysiology of various diseases.
5. Give in own words the pharmacology of drugs acting on autonomic nervous system, central nervous system, cardiovascular system and autacoids.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

General Pharmacology

- Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.
- Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

UNIT II **12 Hours**

Neurotransmission

- General aspects and steps involved in neurotransmission.
- Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
- Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems.

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT III **12 Hours**

Central nervous system Pharmacology

- General and local anesthetics
- Sedatives and hypnotics, drugs used to treat anxiety.
- Depression, psychosis, mania, epilepsy, neurodegenerative diseases
- Narcotic and non-narcotic analgesics

UNIT IV **12 Hours**

Cardiovascular Pharmacology

- Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia
- Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs

UNIT V **12 Hours**

Autocoid Pharmacology

- The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins, Opioid autocoids
- Pharmacology of antihistamines, 5HT antagonists

Suggested Readings^: (Latest Edition)

1. Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of Therapeutics, New York: Mc Graw Hill, Pergamon Press.
2. Golan, D.E., Tashjian, A.H., Armstrong, E.J., Armstrong, A.W. Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy. Philadelphia: Lippincott Williams & Wilkins Publishers.
3. Katzung, B.G. Basic and Clinical Pharmacology, New York: McGraw Hill.
4. Gibaldi, M., Prescott, L. Hand book of Clinical Pharmacokinetics. ADIS Health Science Press.
5. Shargel, L. Andrew B.C. Yu. Applied biopharmaceutics and Pharmacokinetics. New York: Mc Graw Hills Publishers.
6. Smith D.G., Aronson, J. Oxford textbook of Clinical Pharmacology. London, UK: Oxford University Press.
7. Speight, T.M. Holford, N.H.G. Avery's Drug Treatment. Wiley India.
8. Dipiro, J.T., Talbert, R.L., Yee, G.C., Matzke, G.R. Wells, B.G., Posey, M.L. Pharmacotherapy: A Pathophysiologic approach. New York: Mc Graw Hills Publishers.
9. Kumar, V. Abbas, A.K., Aster, J.C. Robbins & Cortan Pathologic Basis of Disease. Elseveir Publishers.
10. Srivastava, S.K. Complete Textbook of Medical Pharmacology. APC Avichal Publishing Company
11. Tripathi, K.D. Essentials of Medical Pharmacology. New Delhi: Jaypee Publishers.
12. Charles C.R., Stitzel, R.E. Modern Pharmacology with Clinical Applications. Philadelphia: Lippincott Williams & Wilkins Publishers.
13. Rowland, M., Tozer, T.N. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications. Philadelphia: Lippincott Williams & Wilkins Publishers.
14. Kwon, Y. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists. New York : Springer Science.
15. Herfindal, E.T., Gourley. Text book of Therapeutics, Drug and Disease Management. Williams and Wilkins Publication.

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(M.Pharm. - Pharmacology)
(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPL103T**
Course Title	**Pharmacological and Toxicological Screening Methods- I**

Scope:

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Course Objectives:

Upon completion of the course the student shall be able to -

1. Appraise the regulations and ethical requirement for the usage of experimental animals.
2. Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals.
3. Describe the various newer screening methods involved in the drug discovery process.
4. Appreciate and correlate the preclinical data to humans.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Understand pharmacology, physiology and pathophysiology of disease qualitatively and quantitatively
2. Demonstrate the skills for handling and use of small animals for experiments as per ethical guidelines and interpret data obtained for human co-relation.
3. Interpret results of pharmacometric evaluation of novel drugs
4. Evaluate various drugs for their pharmacological and toxicological actions using animals models to extrapolate them with human
5. Propose pharmacological screening of novel drugs.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Laboratory Animals

- Common laboratory animals: Description, handling and applications of different species and strains of animals
- Transgenic animals: Production, maintenance and applications
- Anaesthesia and euthanasia of experimental animals.
- Maintenance and breeding of laboratory animals
- CPCSEA guidelines to conduct experiments on animals
- Good laboratory practice
- Bioassay-Principle, scope and limitations and methods

UNIT II **12 Hours**

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

- General principles of preclinical screening.
- CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants,

anxiolytics, anti-psychotics, anti-epileptics and nootropics.

- Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis.
- Drugs acting on Autonomic Nervous System.

UNIT III **24 Hours**

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

- Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti-allergics.
- Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents.
- Gastrointestinal drugs: anti-ulcer, anti-emetic, anti-diarrheal and laxatives.
- Cardiovascular Pharmacology: anti-hypertensives, anti-arrythmics, antianginal, anti-atherosclerotic agents and diuretics.
- Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic, and anti-cancer agents, Hepatoprotective screening methods.

UNIT IV **12 Hours**

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

- Immunomodulators, Immunosuppressants and Immunostimulants.
- General principles of immunoassay: Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin
- Limitations of animal experimentation and alternate animal experiments.
- Extrapolation of in vitro data to preclinical and preclinical to humans

Suggested Readings^: (Latest Edition)

1. Burn, J.H., Finney D.J., Goodwin. I.G. Biological standardization. London: Oxford University Press.
2. Turner, R. A., Hebborn, P. Screening Methods in Pharmacology. New York: Academic Press
3. Laurence, D. R., Bacharach, A. L. Evaluation of Drug Activities: Pharmacometrics. London: Academic Press.
4. Schwartz A. Methods in Pharmacology. Plenum New York.
5. Ghosh, M.N. Fundamentals of Experimental Pharmacology. Kolkata: Hilton & Company.
6. McLeod, L. J. Pharmacological Experiment on Intact Preparations. London: Churchill Livingstone.
7. Vogel, H.G. Drug Discovery and Evaluation: Pharmacological Assays. Berlin Heidelberg, Germany: Springer-Verlag.
8. Goyal, R.K. Experimental Pharmacology. Ahmedabad: B. S. Shah Prakashan.
9. Gupta S. K. Preclinical evaluation of new drugs. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd.
10. Kulkarni, S.K. Handbook of Experimental Pharmacology. Delhi: Vallabh Prakashan.
11. Kulkarni, S.K. Practical Pharmacology and Clinical Pharmacy. Delhi: Vallabh Prakashan.
12. Gross, D.R. Animal Models in Cardiovascular Research. London, UK: Kluwer Academic Publishers.
13. Chatterjee, T. K. Rodents for Pharmacological Experiments. Hyderabad: PharmaMed Press.
14. Medhi, B., Prakash, A. Practical Manual of Experimental and Clinical Pharmacology. New Delhi: Jaypee Brothers Medical Publishers Pvt. Ltd.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ This is not an exhaustive list

(M.Pharm. - Pharmacology)
(Semester - I)

L	T	P	C
4	-	-	4

Course Code	**MPL104T**
Course Title	**Cellular and Molecular Pharmacology**

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Course Objectives:

Upon completion of the course, the student shall be able to -

1. Explain the receptor signal transduction processes.
2. Explain the molecular pathways affected by drugs.
3. Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
4. Demonstrate molecular biology techniques as applicable for pharmacology.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Explain the signal transduction mechanisms.
2. Describe pharmacogenomics, proteomic and immunotherapeutic and their applications.
3. Demonstrate the molecular mechanism of pathways affected by various drugs.
4. Discuss the molecular biology techniques as applicable for pharmacology
5. Determine the regulating mechanisms involved in cellular function.
6. Evaluate the applicability of molecular pharmacology and biomarkers in drug discovery process.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Cell biology

- Structure and functions of cell and its organelles
- Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing
- Cell cycles and its regulation.
- Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.
- Necrosis and autophagy

UNIT II **12 Hours**

Cell signaling

- Intercellular and intracellular signaling pathways.
- Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
- Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5- trisphosphate, (IP3), NO, and diacylglycerol.
- Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway

UNIT III **12 Hours**

Principles and applications of genomic and proteomic tools

- DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,
- Recombinant DNA technology and gene therapy
- Basic principles of recombinant DNA technology - Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.
- Gene therapy - Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

UNIT IV **12 Hours**

Pharmacogenomics

- Gene mapping and cloning of disease gene.
- Genetic variation and its role in health/ pharmacology
- Polymorphisms affecting drug metabolism
- Genetic variation in drug transporters
- Genetic variation in G protein coupled receptors
- Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics

- Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

UNIT IV **12 Hours**

Cell culture techniques

- Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.
- Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays
- Principles and applications of flow cytometry

Biosimilars

Suggested Readings^: (Latest Edition)

1. Cooper, G. M. Hausman, R.E. The Cell: A Molecular Approach. Sinauer Associates
2. Licinio, J. Wong, Ma-Li. Pharmacogenomics. USA: John Wiley & Sons.
3. Bradshaw, R.A. Handbook of Cell Signaling. Amsterdam: Elsevier.
4. Dickenson, J. Molecular Pharmacology. Chichester: Wiley-Blackwell.
5. Helgason, C.D. Miller C.L. Basic Cell Culture Protocols. USA: Springer Science+Business Media, LLC: Humana.
6. Davis, J. M. Basic Cell Culture. London, UK: Oxford University Press.

7. Masters, J. R. W. Animal Cell Culture. London, UK: Oxford University Press.
8. Ausuvel, F.M., Brent, R., Kingston, R. E. Moore, D. D., Seidman, J.D., Smith, J., Struhl, K. Current Protocols in Molecular Biology. USA: John Wiley & Sons.

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^ This is not an exhaustive list

(M.Pharm: Pharmacology)
(Semester - I)

L	T	P	C
-	-	12	6

Course Code	**MPL105P**
Course Title	**Pharmacological Practical I**

Syllabus: **Teaching hours: 180 Hours**

1. Analysis of pharmacopocial compounds and their formulations by UV Vis spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares

Revised Syllabus

(MPharm in Pharmacology)

Semester - I

L	T	P	C
-	-	12	06

Course Code	**MPL105P**
Course Title	**Pharmacological Practical I**

Syllabus: **Total Teaching hours: 180h**

Unit		Syllabus	Teaching hours
Unit-I	1.	Introduction to animal handling and various routes of drug administration, techniques of blood sampling, anesthesia and euthanasia of experimental animals	45 hours
	2.	Evaluation of local anesthetic activity	
	3.	Functional observation battery tests (modified Irwin test)	
	4.	Evaluation of CNS stimulant/CNS depressant activity	
	5.	Evaluation of antipsychotic activity	
	6.	Evaluation of diuretic activity	
	7.	Evaluation of analgesic activity	
	8.	Evaluation of anxiogenic/ anxiolytic activity	
	9.	Evaluation of CNS drugs by different mazes	
	10.	Evaluation of anticonvulsant activity.	
	11.	Evaluation of skeletal muscle relaxant activity	
Unit-II	1.	Evaluation of mydriatic and miotic activity.	45 hours
	2.	Collection of biological fluids and isolation of various tissues and organs	
	3.	Evaluation of antiulcer activity by pylorus ligation method	
	4.	Enzyme based in-vitro assays (MPO)	
	5.	Enzyme based in-vitro assays (AChEs)	
	6.	Enzyme based in-vitro assays (α amylase)	
	7.	Enzyme based in-vitro assays (α glucosidase)	
	8.	Oral glucose tolerance test	
	9.	Estimation of proteins by Bradford/Lowry's in biological samples	
	10.	Enzyme inhibition and induction activity	
	11.	Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares	
Unit-III	1.	Isolation and identification of DNA from various sources	45 hours
	2.	Estimation of RNA/DNA by UV Spectroscopy	
	3.	Isolation and identification of RNA from various sources	
	4.	DNA fragmentation assay by agarose gel electrophoresis	
	5.	Gene amplification by PCR	
	6.	Protein quantification Western Blotting	
	7.	DNA damage study by Comet assay	
	8.	Apoptosis determination by fluorescent imaging studies	
Unit-IV	1.	Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques	45 hours

(HPLC).

2. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
3. Analysis of pharmacopoeial compounds and their formulations by UV spectrophotometer.
4. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
5. Experiments based on HPLC
6. Experiments based on Gas Chromatography
7. Estimation of riboflavin/quinine sulphate by Fluorimetry
8. Estimation of sodium/potassium by flame photometry

Suggested Readings/ References:
^ (Latest Edition)

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Ghosh, M. N. Fundamentals of Experimental Pharmacology. Kolkata: Hilton & Company.
3. Kulkarni, S. K. Hand book of Experimental Pharmacology. Delhi: Vallabh Prakashan.
4. Vogel, H. G. Drug Discovery and Evaluation: Pharmacological Assays. Berlin: Springer.
5. Silverstein, R. M., Webster, F. X., Kiemle, D. J., Bryce, D. L. Spectrometric Identification of Organic Compounds. USA: John Wiley & Sons.
6. Skoog, D., Holler, F., Nieman, T. Principles of Instrumental Analysis. Philadelphia, NY: Hartcourt Brace.
7. Mendham, J, Denney, R, Barnes, J, Thomas, M. Vogel's Textbook of Quantitative Chemical Analysis. Harlow (England): Prentice Hall, an imprint of Pearson Education.
8. Helgason, C. D., Miller, C. L. Basic Cell Culture Protocols. New York: Humana Press.
9. Davis, J. M. Basic Cell Culture: A Practical Approach. London, UK: Oxford University Press.
10. Masters, J. R. Animal Cell Culture: A Practical Approach. London, UK:: Oxford University Press.
11. Medhi, B., Prakash, A. Practical Manual of Experimental and Clinical Pharmacology. New Delhi: Jaypee Brothers Medical Pvt. Ltd.

^ This is not an exhaustive list

NIRMA UNIVERSITY
Institute of Pharmacy
Teaching & Examination Scheme *(M. Pharm - Pharmacology)*

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MPL201T	Advanced Pharmacology-II	4	-	-	4	3.0	-	0.60	-	0.40
2	MPL202T	Pharmacological and Toxicological Screening Methods-II	4	-	-	4	3.0	-	0.60	-	0.40
3	MPL203T	Principles of Drug Discovery	4	-	-	4	3.0	-	0.60	-	0.40
4	MPL204T	Clinical research and Pharmacovigilance	4	-	-	4	3.0	-	0.60	-	0.40
5	MPL205P	Pharmacological Practical- II	-	12	-	6	-	6.0	-	1.00	-
6	MPL206S	Seminar / Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**		**26**					
			35								

L: *Lectures*, P/T: *Practicals/Tutorial*, C: *Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

w.e.f. academic year 2017-2018 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL201T**
Course Title	**Advanced Pharmacology-II**

Scope:

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved.

Objectives:

Upon completion of the course the student shall be able to -

1. Discuss the pathophysiology and pharmacotherapy of certain diseases.
2. Explain the mechanism of drug actions at cellular and molecular level.
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Explain mechanisms of action, adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.
2. Relate pathogenesis of various diseases with their treatment.
3. Utilize the knowledge of chronopharmacology for treatment of various diseases.
4. Develop understanding of role of oxidative stress in various disease and their treatment.
5. Discuss pharmacological actions of different drugs useful for therapy of various diseases.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Endocrine Pharmacology:

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

UNIT II **18 Hours**

Chemotherapy:

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics, Antifungal, antiviral, and anti-TB drugs, Drugs used in protozoal infections, Drugs used in the treatment of helminthiasis, Chemotherapy of cancer.

UNIT III **06 Hours**

Immunopharmacology:

Cellular and biochemical mediators of inflammation and immune response, Allergic or hypersensitivity reactions, Pharmacotherapy of asthma and COPD, Immunosuppressants and Immunostimulants.

UNIT IV **12 Hours**

GIT Pharmacology:

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology:

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer.

UNIT V **12 Hours**

Free radicals Pharmacology:

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus.

Suggested Readings^: (Latest Edition)

1. Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, New York: Mc Graw Hill, Pergamon Press.
2. Golan, D.E., Tashjian, A.H., Armstrong, E.J., Armstrong, A.W. *Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy.* Philadelphia: Lippincott Williams & Wilkins Publishers.
3. Katzung, B.G. *Basic and Clinical Pharmacology*, New York: McGraw Hill.
4. Gibaldi, M., Prescott, L. *Hand book of Clinical Pharmacokinetics*. ADIS Health Science Press
5. Herfindal, E.T., Gourley. *Text book of Therapeutics, Drug and Disease Management.* Williams and Wilkins Publication.
6. Shargel, L. Andrew B.C. Yu. *Applied biopharmaceutics and Pharmacokinetics*. New York: Mc Graw Hills Publishers.
7. Kwon, Younggil. *Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.* New York: Kluwer Academic/Plenum.
8. Kumar, V. Abbas, A.K., Aster, J.C. *Robbins & Cortan Pathologic Basis of Disease*. Elsevier Publishers.
9. Srivastava, S.K. *Complete Textbook of Medical Pharmacology*. APC Avichal Publishing Company

10. Tripathi, K.D. *Essentials of Medical Pharmacology*. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd.

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^ this is not an exhaustive list

(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL202T**
Course Title	**Pharmacological and Toxicological Screening Methods- II**

Scope:
This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:
Upon completion of the course the student shall be able to –

1. Explain the various types of toxicity studies.
2. Appreciate the importance of ethical and regulatory requirements for toxicity studies.
3. Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Define various types of toxicity studies and their mechanism of action.
2. Demonstrate toxicity of various drugs qualitatively and quantitatively.
3. Illustrate the skills and understanding required to conduct preclinical toxicity studies as per the regulatory and ethical requirements.
4. Interpret results of toxicokinetics of novel drugs.
5. Evaluate various drugs for their safety pharmacological and toxicological actions using animal models to extrapolate them with human beings.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive), Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development

UNIT II **12 Hours**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies

UNIT III **12 Hours**

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

UNIT IV **12 Hours**

IND enabling studies (IND studies) - Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

UNIT V **12 Hours**

Toxicokinetics - Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

Suggested Readings^: (Latest Edition)

1. World Health Organization. *Handbook: good laboratory practice (GLP): quality practices for regulated non-clinical research and development.* World Health Organization.
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Ng, R. *Drugs: from discovery to approval.* John Wiley & Sons, New Jersey.
4. Lower, G. M., & Bryan, G. T., *Animal Models in Toxicology*, 3rd Edition, OECD test guidelines.
5. Stine, K. E., & Brown, T. M. *Principles of toxicology.* CRC Press, United states.
6. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

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^ this is not an exhaustive list

(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL203T**
Course Title	**Principles of Drug Discovery**

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

Upon completion of the course the student shall be able to –

1. Explain various stages of drug discovery.
2. Appreciate importance of the role of genomics, proteomics and bioinformatics in drug discovery.
3. Explain various targets for drug discovery.
4. Explain various lead seeking method and lead optimization.
5. Appreciate the importance of the role of computer aided drug design in drug discovery.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Describe the flow and methods of drug discovery and development process and their challenges.
2. Demonstrate role of genomics, proteomics and bioinformatics in drug discovery.
3. Explain rational drug design based on the understanding of three-dimensional (3D) structures and physicochemical properties of drugs and target.
4. Apply various CADD in-silico techniques like pharmacophore modeling, QSAR, molecular docking, homology modeling etc. for the lead identification and optimization.
5. Make use of rationale and practical considerations for prodrug designing.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

An overview of modern drug discovery process:

Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

UNIT II **12 Hours**

Lead Identification:

Combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT III **12 Hours**

Rational Drug Design:

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

UNIT IV **12 Hours**

Molecular docking:

Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

UNIT V **12 Hours**

QSAR Statistical methods:

Regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design:

Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

Suggested Readings^: (Latest Edition)

1. Sioud, M. *Target Discovery and Validation Reviews and Protocols: Emerging Molecular Targets and Treatment Options*, Volume 2. Totowa: Humana Press Inc., New Jersey.
2. León, D., & Markel, S. (Eds.). *In Silico Technologies in Drug Target Identification and Validation*. CRC Press, United States
3. DiStefano, J. K., *Disease Gene Identification. Methods and Protocols*. Springer New York Dordrecht Heidelberg, London.
4. Mannhold, R., Krogsgaard-Larsen, P., & Timmerman, H. *QSAR: Hansch analysis and related approaches* (Vol. 1). John Wiley & Sons, New Jersey.
5. Bures, M. G. *Structure-based Ligand Design* Edited by K. Gubernator and H.-J. Bohm. Wiley-VCH, Weinheim.
6. Parrill, A. L., & Reddy, M. R. (Eds.). *Rational drug design: novel methodology and practical applications*. American Chemical Society, United States
7. Turner R. J. *New drug development design, methodology and, analysis*. John Wiley & Sons, Inc., New Jersey.

8. Stroud, R. M. & Moore, J. M. *Computational and Structural Approaches to Drug Discovery: Ligand-Protein Interactions.* RCS Publishers.
9. Smith, H. J. & Williams, H. *Introduction to the principles of drug design and action.* CRC Press, Taylor & Francis.
10. Patrick, G. L. *An introduction to medicinal chemistry.* Oxford University Press.

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^ this is not an exhaustive list

(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPL204T**
Course Title	**Clinical Research and Pharmacovigilance**

Scope:
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:
After completion of course student is able to know about –
1. Explain the regulatory requirements for conducting clinical trial.
2. Demonstrate the types of clinical trial designs.
3. Explain the responsibilities of key players involved in clinical trials.
4. Execute safety monitoring, reporting and close-out activities.
5. Explain the principles of Pharmacovigilance.
6. Detect new adverse drug reactions and their assessment.
7. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -
1. Understand regulatory perspectives of clinical trials and research.
2. Explain pharmacoepidemiology, pharmacoeconomics, safety pharmacology.
3. Summarize basic aspects, terminologies and establishment of Pharmacovigilance.
4. Discuss methods, ADR reporting and tools used in Pharmacovigilance.
5. Develop clinical trial documentation including ADR reporting.

6. Elaborate about clinical trials.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **10 Hours**

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process.

UNIT II **12 Hours**

Clinical Trials:

Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT III **12 Hours**

Clinical Trial Documentation:

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT.

Adverse Drug Reactions:

Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

UNIT IV **10 Hours**

Basic aspects, terminologies and establishment of Pharmacovigilance:

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centers in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT V **10 Hours**

Methods, ADR reporting and tools used in Pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

UNIT VI **06 Hours**

Health Economics and Outcomes Research:

Pharmacoepidemiology, pharmacoeconomics, safety pharmacology.

Suggested Readings^: (Latest Edition)

1. Central Drugs Standard Control Organization- *Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India.* New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; June 2016.
3. *Ethical Guidelines for Biomedical Research on Human Subjects 2000.* Indian Council of Medical Research, New Delhi.
4. Machin, D., Simon D., and Sylvan G., eds. *Textbook of Clinical Trials.* USA. John Wiley & Sons.
5. Rondel, R. K., Varley, S. A., & Webb, C. F. (Eds.). *Clinical Data Management.* New York: Wiley.
6. Lloyd, J., & Raven, A. (Eds.). *Handbook of Clinical Research.* Churchill Livingstone.
7. Di Giovanna, I., & Hayes, G. *Principles of Clinical Research.* UK, Routledge
8. Verma, S., Gulati, Y. *Fundamentals of Pharmacovigilance.* New Delhi, Paras Medical Publishers.
9. Arora, D. *Pharmacovigilance: An Industry Perspective.* Mumbai, Pharma Publishers.

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^ this is not an exhaustive list

(M. Pharm - Pharmacology)
(Semester - II)

L	T	P	C
-	-	12	6

Course Code	**MPL205P**
Course Title	**Pharmacological Practical-II**

Syllabus: **Teaching hours: 180 Hours**

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations.
9. Recording of rat BP and heart rate.

10. Recording of rat ECG.
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial. (3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting.

Suggested Readings^: (Latest Edition)

1. Ghosh, M. N. *Fundamentals of Experimental Pharmacology*. Kolkatta: Hilton & Company
2. Kulkarni, S. K. *Hand book of Experimental Pharmacology*. Delhi: Vallabh Prakashan
3. Kitchen, Von Ian. *Textbook of in Vitro Practical Pharmacology*. Oxford: Blackwell Scientific Publications.
4. Rahman, A., Choudhary, I. M. *Bioassay techniques for drug development*. - William J. Thomsen - Harwood Acad. Publ.
5. Shargel, L. Andrew B.C. Yu. *Applied Biopharmaceutics and Pharmacokinetics*. New York: Mc Graw Hills Publishers.
6. Kwon, Younggil. *Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists*. New York: Kluwer Academic/Plenum, Print.
7. https://www.who-umc.org/

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Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M.Pharm. - Pharmacology)

Semester - III

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MPL302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MPL303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MPL304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPL401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MPL402P	Research work and Colloquium	-	31	-	16	-	1.0		1.0	-
3	MPL403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm)
(Semester - III)

L	T	P	C
4	-	-	4

Course Code	MRM301T
Course Title	Research Methodology & Biostatistics

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. List various types of research and significance of review of literature
2. Describe the parametric and non- parametric tests related to biostatistics
3. Discuss various types of medical research
4. Explain CPCSEA guidelines for laboratory animal facility
5. Express the role of declaration of Helsinki

Syllabus: **Teaching hours: 60 Hours**

UNIT I **15 Hours**

General Research Methodology: Research, objective, protocol design, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding and related labelling techniques, conduct, monitoring, analysis and interpretation, reporting and record keeping, Scientific writing.

UNIT II **20 Hours**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values, application based case studies.

UNIT III **10 Hours**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT IV **05 Hours**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals, Import of animals.

UNIT V **10 Hours**

General Guidelines of clinical research, ICH E9 guidelines, Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Suggested Readings^: (Latest Edition)

1. Best, J.W., Kahn, J.V., *Research In Education*. New Delhi, Prentice Hall of India Pvt. Ltd.
2. Halton, M., *Presentation Skills*. Indian Society for Institute Education
3. Mcfarlane, G., *A Practical Introduction to Copyright*. McGraw Hill
4. Davis, R.M., *Thesis Projects in Science and Engineering*. St. Martin's Press.
5. Anderson, J., *Thesis and Assignment Writing*. John Wiley & Sons.

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NIRMA UNIVERSITY
INSTITUTE OF PHARMACY
PROGRAMME: MASTER OF PHARMACY IN PHARMACEUTICAL ANALYSIS

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of *(M.Pharm- Pharmaceutical Analysis)*

Semester - I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPA101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
2	MPA102T	Advanced Pharmaceutical Analysis	4	-	-	4	3.0	-	0.60	-	0.40
3	MPA103T	Pharmaceutical Validation	4	-	-	4	3.0	-	0.60	-	0.40
4	MPA104T	Food Analysis	4	-	-	4	3.0	-	0.60	-	0.40
5	MPA105P	Pharmaceutical Analysis Practical I	-	12	-	6	-	6.0	-	1.00	-
6		Seminar/Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	-	**26**	-	-	-	-	-
			35								

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

w.e.f. academic year 2017-18 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M.Pharm. - Pharmaceutical Analysis)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPA101T**
Course Title	**Modern Pharmaceutical Analytical Techniques**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

1. The analysis of various drugs in single and combination dosage forms
2. Theoretical and practical skills of the instruments

Course Learning Outcomes (CLO):

At the end of the course, students will be able to-

1 Recall the fundamental theory of different spectroscopic techniques.
2 Recognize the fundamentals, instrumentation and applications of various chromatographic methods
3 Discuss the instrumentation and application of various spectroscopic techniques
4 Describe various electrophoresis and X-ray methods
5 Apply the knowledge of various thermal and electro analytical methods in analysis of drugs and excipients

Syllabus: **Teaching hours: 60 Hours**

UNIT-I **10 Hours**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy Difference/ Derivative spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data interpretation.

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy:

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT – II **10 Hours**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.

UNIT – III **10 Hours**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT – IV **10 Hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

UNIT – V **10 Hours**

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

UNIT – VI **10 Hours**

Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

Suggested Readings^: (Latest edition)

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., & Bryce, D. L.. Spectrometric Identification of Organic Compounds. Johnwiley & sons.
2. Skoog, D. A. H., James, F., & Nieman, T. A. Principles of Instrumental Analysis. Eastern press.
3. Hobart, W. H., Merritt LL, Dean John. A., Instrumental Methods of Analysis. CBS publishers.
4. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.
5. Kemp, W. Organic Spectroscopy. ELBS.
6. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. CBS Publishers.
7. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.
8. Kalsi, P. S. Spectroscopy of Organic Compounds. Wiley Estern Ltd.
9. Connors, K. A. A Textbook of Pharmaceutical Analysis. NJ: Johnwiley and sons.

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^ this is not an exhaustive list

(M.Pharm. - Pharmaceutical Analysis)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPA102T**
Course Title	**Advanced Pharmaceutical Analysis**

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

1. Appropriate analytical skills required for the analytical method development.
2. Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
3. Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

Proposed

(M.Pharm. - Pharmaceutical Analysis)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPA102T**
Course Title	**Advanced Pharmaceutical Analysis**

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

1. Appropriate analytical skills required for the analytical method development.
2. Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
3. Analysis of impurities in drugs, residual solvents and stability studies of drugs and **biological products**

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Define the impurities and classification of the impurities
2. Recognize the basic principle, preparation of antibodies and applications of immunoassays
3. Understand stability aspects for drug substances and drug products.
4. Describe the analytical method development and validation for stability testing as per regulatory guidelines
5. Discuss stability testing for phytopharmaceuticals
6. Explain the analysis of various vaccines, **biological products and biotechnologically derived products.**

Syllabus: **Teaching hours**: **60 Hours**

UNIT – I **10 Hours**

Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT – II **10 Hours**

Elemental impurities: Element classification, control of elemental impurities, Potential

Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation.

Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

UNIT – III **10 Hours**

Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

UNIT – IV **5 Hours**

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

UNIT – V **15 Hours**

Biological tests and assays of the following:

- Adsorbed Diphtheria vaccine
- Human anti haemophilic vaccine
- Rabies vaccine
- **Tetanus vaccine and its related products**
- Oxytocin
- Heparin sodium IP
- Antivenom.

Physico chemical characterization of macromolecules:

Covalent structure determination: Peptide mapping, N-Terminal sequencing, Disulfide bond characterization, Post translational modifications, Higher order structure and folding, Stability related structural changes determination, Cell based and non-cell based functional Bioassays

- **Erythropoietin concentrated solution and injection**
- **Filgrastim concentrated solution and injection**
- **Follicle stimulating Growth hormone concentrated solution and injection**
- **Interferon alfa-2 concentrated solution and injection**

UNIT – VI **10 Hours**

Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

Surface Plasmon Resonance (SPR) spectroscopy for affinity studies (Principles and procedures)

Analytical Ultracentrifugation (AUC), Principle and applications

Circular Dichroism (CD) spectroscopy, Principle and applications

Suggested Readings^: (Latest edition)

1. Mendham, J. Vogels Textbook of Quantitative Chemical Analysis. Pearson Education India.
2. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.
3. Connors, K. A. A Textbook of Pharmaceutical Analysis. NJ: Johnwiley and sons.
4. Higuchi, T., Bodin, J. I., & Brochmann-Hanssen, E. Pharmaceutical Analysis. Interscience Publishers.
5. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. CBS Publishers.
6. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.
7. Carratt, D. C. The Quantitative Analysis of Drugs. CBS Publishers.
8. Indian Pharmacopoeia,. Government of India. Ministry of health and family welfare.
9. Methods of Sampling and Microbiological Examination of Water, First Revision, BIS.
10. Snyder, L. R., Kirkland, J. J., & Glajch, J. L. Practical HPLC Method Development. John Wiley & Sons.
11. O. Brien, M., McCauley, J., & Cohen, E. Analytical Profile of Drug Substances, Klaus Florey.
12. Brittain, H. G. Analytical Profiles of Drug Substances and Excipients (Vol. 23). Academic Press.
13. Chamberlain, J. The Analysis of Drugs in Biological Fluids 2nd Edition. CRC press.
14. ICH Guidelines for impurity profiles and stability studies
15. Indian Pharmacopoeia, Volume III, Indian Pharmacopoeial commission, Ghaziabad, New Delhi

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^ this is not an exhaustive list

- PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

UNIT – VI **10 Hours**

Immunoassays (IA): Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

Suggested Readings^: (Latest edition)

1. Mendham, J. Vogels Textbook of Quantitative Chemical Analysis. Pearson Education India.
2. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part II Fourth Edition (Vol. 2). A&C Black.
3. Connors, K. A. A Textbook of Pharmaceutical Analysis. NJ: Johnwiley and sons.
4. Higuchi, T., Bodin, J. I., & Brochmann-Hanssen, E. Pharmaceutical Analysis. Interscience Publishers.
5. Shethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. CBS Publishers.
6. Munson, J. W. Pharmaceutical Analysis: Modern Methods (Vol. 11). CRC Press.
7. Carratt, D. C. The Quantitative Analysis of Drugs. CBS Publishers.
8. Indian Pharmacopoeia,. Government of India. Ministry of health and family welfare.
9. Methods of Sampling and Microbiological Examination of Water, First Revision, BIS.
10. Snyder, L. R., Kirkland, J. J., & Glajch, J. L. Practical HPLC Method Development. John Wiley & Sons.
11. O. Brien, M., McCauley, J., & Cohen, E. Analytical Profile of Drug Substances, Klaus Florey.
12. Brittain, H. G. Analytical Profiles of Drug Substances and Excipients (Vol. 23). Academic Press.
13. Chamberlain, J. The Analysis of Drugs in Biological Fluids 2nd Edition. CRC press.
14. ICH Guidelines for impurity profiles and stability studies

L= Lecture, T= Tutorial, P= Practical, C= Credit

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(M.Pharm. - Pharmaceutical Analysis)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPA103T**
Course Title	**Pharmaceutical Validation**

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

1. Explain the aspect of validation
2. Carryout validation of manufacturing processes
3. Apply the knowledge of validation to instruments and equipments
4. Validate the manufacturing facilities

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Define qualification for the analytical instruments and laboratory equipments
2. Understand different types of validation
3. Explain water and HVAC system in pharmaceutical industry.
4. Describe the analytical method development and validation for drug substance and drug product as per regulatory guidelines
5. Discuss IPR issues, patent filing, copyright and trademarks

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT – II **12 Hours**

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC,

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT – III **12 Hours**

Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT – IV **12 Hours**

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

UNIT - V **12 Hours**

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention

patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

Suggested Readings^: (Latest edition)

1. Loftus, B. T., & Nash, R. A. Pharmaceutical Process Validation. Drugs and Pharm Sci. Series (Vol. 129) M. Dekker.
2. Lachman, L., Lieberman, H. A., & Kanig, J. L. The Theory and Practice of Industrial Pharmacy. Philadelphia: Lea & Febiger. Varghese Publishing House.
3. Terveeks, & Deeks. Validation Master Plan. Davis Harwood International Publishing.
4. Carleton, F. J., & Agalloco, J. P. Validation of Aseptic Pharmaceutical Processes, Marcel Dekker.
5. Levin Michael, Pharmaceutical Process Scale-Up II, Drugs and Pharm. Sci. Series (Vol. 157). Marcel Dekker Inc.
6. Validation Standard Operating Procedures, Step by step guide for achieving compliance in the pharmaceutical, Medical device and biotech industries. Syed Imtiaz Haider. CRC Press.
7. Cloud, P. Pharmaceutical Equipment Validation: The Ultimate Qualification Guidebook. CRC Press.
8. Carleton, F. J., & Agalloco, J. P. Validation of Pharmaceutical Processes: Sterile Products. Informa Healthcare.
9. Chan, C. C., Lee, Y. C., Lam, H., & Zhang, X. M. (Eds.). Analytical Method Validation and Instrument Performance Verification. John Wiley & Sons.

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^ this is not an exhaustive list

(M.Pharm. - Pharmaceutical Analysis)
(Semester – I)

L	T	P	C
4	-	-	4

Course Code	**MPA104T**
Course Title	**Food Analysis**

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

1. Food constituents
2. Food additives
3. Finished food products
4. Pesticides in food
5. And also student shall have the knowledge on food regulations and legislations

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Recall and classify different carbohydrate and protein
2. Discuss different types of lipid and vitamins along with general method of analysis
3. Describe fundamentals of standards and quality for food products and additives.
4. Tell food legislation
5. Apply different analytical methods for dairy products and beverages
6. Use analytical methods for the determination of pesticides.

Syllabus: **Teaching hours: 60 Hours**

UNIT – I **12 Hours**

Carbohydrates: Chemistry & classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates

Proteins: Chemistry and classification of amino acids and proteins, Physico- Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins

UNIT – II **12 Hours**

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series.

UNIT – III **12 Hours**

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

UNIT – IV **12 Hours**

General Analytical methods: General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

UNIT – V **12 Hours**

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

Revised Syllabus

MPharm. Pharmaceutical Analysis

Semester - I

L	T	P	C
0	0	12	6

Course Code:	**MPA105P**
Course Title:	**Pharmaceutical Analysis Practical - I**

Syllabus: **Total Teaching hours: 180**

Unit	Syllabus	Teaching hours
Unit-I		**51**
	1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (Paracetamol)	3
	2. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (Diclofenac sodium)	3
	3. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (Aspirin)	3
	4. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (Sulphacetamide)	3
	5. Simultaneous estimation of Sodium benzoate and caffeine by UV spectrophotometry	6
	6. Simultaneous estimation of Paracetamol and Diclofenac by UV spectrophotometry	6
	7. Estimation of riboflavin/quinine sulphate by fluorimetry	3
	8. Estimation of sodium/potassium by flame photometry	3
	9. Assay of official compounds by different titrations (Sulphamethoxazole from Co-Trimoxazole tablets)	3
	10. Assay of official compounds by different titrations (Bisacodyl suppository and/or Autotitrator Practical)	3
	11. Colorimetric determination of drugs by using different reagents (Estimation of Sulpha drug with Bratton Marshall Reagent)	3
	12. Colorimetric determination of drugs by using different reagents (Estimation of Salicylic acid using $FeCl_3$)	3
	13. 2^{nd} order structure determination of selected biotherapeutics using FTIR spectroscopy.	3

	14. Quantification of selected drug from tablet formulation using HPLC	6
Unit-II		**30**
	1. Impurity profiling of selected API using HPLC method	6
	2. Estimation of residual solvents using Gas chromatography	6
	3. Photostability study of ciprofloxacin in solid and liquid state	6
	4. Hands on training for quantification of impurities using RRF value	3
	5. Determination of degradation rate constant for given sample.	3
	6. Finger print profile of selected medicinal plants using HPTLC method.	6
Unit-III		**48**
	1. Calibration of glasswares	3
	2. Calibration of pH meter	3
	3. Calibration of UV-Visible spectrophotometer	3
	4. Calibration of FTIR spectrophotometer	3
	5. Calibration of HPLC instrument	3
	6. Calibration of GC instrument	3
	7. To search and compilation of existing patents for desloratadine formulations.	3
	8. To search and compilation of existing patents for oxymetazoline formulations.	3
	9. To perform the cleaning validation of various glassware.	3
	10. To perform the cleaning validation of tablet compression machine.	3
	11. To perform the analytical method validation for paracetamol tablets.	3
	12. To perform the analytical method validation for diclofenac tablets.	6
	13. To prepare Standard Operating Procedure for pH and Conductivity meter.	6
	14. To prepare Standard Operating Procedure for UV-Visible spectrophotometer and FTIR spectrophotometer.	3
Unit-IV		**51**
	1. Determination of total reducing sugar	3
	2. Determination of proteins	3
	3. Quantitative determination of hydroxyl group.	3
	4. Quantitative determination of amino group	3
	5. Determination of pesticide residue in food products	3
	6. Analysis of natural and synthetic colors in food	3
	7. Analysis of vitamin content in food products	6

	8. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products	6
	9. Determination of fat content and rancidity in food products	6
	10. Testing of adulterants in the oil samples	3
	11. Determination of density and specific gravity of foods	3
	12. Analysis of milk and milk products	3
	13. Analysis of vinegar	3
	14. Determination of food additives like antioxidants, flavoring agents, preservatives etc	3

Suggested Readings/ References: (Latest edition)

1. Indian Pharmacopoeia, Ministry of health and family welfare, Government of India.
2. United States Pharmacopeia, United States Pharmacopeial Convention, USA
3. British Pharmacopoeia, British Pharmacopoeial Commission, UK
4. Beckett, Arnold Heyworth, and John Bedford Stenlake, eds. Practical Pharmaceutical Chemistry: Part I & II.
5. Sethi, P. D. Quantitative analysis of drugs in pharmaceutical formulations, CBS publications, New Delhi.

NIRMA UNIVERSITY

Institute of Pharmacy

Teaching & Examination Scheme *(M. Pharm- Pharmaceutical Analysis)*

Semester - II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
							Duration		Component Weightage		
			L	LPW/PW	T	C	SEE	LPW/PW	CE	LPW/PW	SEE
1	MPA201T	Advanced Instrumental Analysis	4	-	-	4	3.0	-	0.60	-	0.40
2	MPA202T	Modern Bio-Analytical Techniques	4	-	-	4	3.0	-	0.60	-	0.40
3	MPA203T	Quality Control and Quality Assurance	4	-	-	4	3.0	-	0.60	-	0.40
4	MPA204T	Herbal and Cosmetic Analysis	4	-	-	4	3.0	-	0.60	-	0.40
5	MPA205P	Pharmaceutical Analysis Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MPA206S	Seminar/Assignment	-	7	-	4	-	-	-	1.00	-
		Total	**16**	**19**	-	**26**	-	-	-	-	-
			35								

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*
LPW/PW: *Laboratory / Project Work*

SEE: *Semester End Examination*
CE: *Continuous Evaluation*

39

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA201T**
Course Title	**Advanced Instrumental Analysis**

Scope:

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives:

After completion of course student is able to know -

1. Interpretation of the NMR, Mass and IR spectra of various organic compounds.
2. Theoretical and practical skills of the hyphenated instruments.
3. Identification of organic compounds.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the fundamental theory of different chromatographic techniques.
2. Describe the principle, instrumentation and applications of HPLC, HPTLC, SFC and GC methods.
3. Discuss the principle, instrumentation and applications of various biochromatographic methods.
4. Explain the instrumentation and applications of various spectroscopic techniques.
5. Predict the structural information using mass and NMR spectrometry and related hyphenated techniques.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

HPLC:

Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches.

HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

UNIT II **12 Hours**

Biochromatography:

Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography:

Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography:

Principles, instrumentation, pharmaceutical applications.

UNIT III **12 Hours**

Super critical fluid chromatography:

Principles, instrumentation, pharmaceutical applications.

Capillary electrophoresis:

Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

UNIT IV **12 Hours**

Mass spectrometry:

Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

UNIT V **12 Hours**

NMR spectroscopy:

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ^{13}CNMR:

Spin spin and spin lattice relaxation phenomenon. ^{13}C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

Suggested Readings^: (Latest edition)

1. Silverstein, R. M., Webster, F. X., Kiemle, D. J., & Bryce, D. L.. *Spectrometric Identification of Organic Compounds*. Johnwiley & sons.
2. Skoog, D. A. H., James, F., & Nieman, T. A. *Principles of Instrumental Analysis. Eastern press*.
3. Hobart, W. H., Merritt LL, Dean John. A., *Instrumental Methods of Analysis*. CBS publishers.
4. Kemp, W. *Organic Spectroscopy*. ELBS.

5. Sethi, P. D. *HPTLC: High performance thin-layer chromatography; quantitative analysis of pharmaceutical formulations*. CBS publishers & distributors.
6. Sethi, P. D. *Quantitative Analysis of Drugs in Pharmaceutical Formulations*. CBS Publishers.
7. Munson, J. W. *Pharmaceutical Analysis: Modern Methods (Vol. 11)*. CRC Press.
8. Pavia, D. L., Lampman, G. M., Kriz, G. S., & Vyvyan, J. A.. *Introduction to spectroscopy*. Cengage Learning.

L= Lecture, T= Tutorial, P= Practical, C= Credit
^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA202T**
Course Title	**Modern Bio-Analytical Techniques**

Scope:
This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives:
Upon completion of the course, the student shall be able to understand -
1. Extraction of drugs from biological samples.
2. Separation of drugs from biological samples using different techniques.
3. Guidelines for BA/BE studies.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to –
1. Understand the basics of drug extraction methods.
2. Determine the biopharmaceutical factors for drug absorption and drug release.
3. Describe pharmacokinetics and its importance along with toxicokinetics.
4. Discuss the principle techniques and applications of various cell culture methods.
5. Apply bioavailability and bioequivalence principles in drug product performance.
6. Predict the possible metabolite formation of drug product.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Extraction of drugs and metabolites from biological matrices:

General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation:

USFDA and EMEA guidelines.

UNIT II **12 Hours**

Biopharmaceutical Consideration:

Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System.

Solubility:

Experimental methods.

Permeability:

In-vitro, in-situ and In-vivo methods.

UNIT III **12 Hours**

Pharmacokinetics and Toxicokinetics:

Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT IV **12 Hours**

Cell culture techniques:

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

UNIT V **12 Hours**

Metabolite identification:

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

Suggested Readings^: (Latest edition)

1. Chamberlain, J. *The Analysis of Drugs in Biological Fluids*. CRC press.
2. Skoog, D. A., Holler, F. J., & Crouch, S. R. *Principles of instrumental analysis*. Cengage learning.

3. Higuchi, T., Bodin, J. I., & Brochmann-Hanssen, E. *Pharmaceutical analysis*. Interscience Publishers.
4. Munson, J. W. *Pharmaceutical analysis: modern methods (Vol. 11)*. CRC Press.
5. Snyder, L. R., Kirkland, J. J., & Glajch, J. L. *Practical HPLC method development*. John Wiley & Sons.
6. Adamovics, J. A. *Chromatographic analysis of pharmaceuticals (Vol. 74)*. CRC Press.
7. Bertholf, R., & Winecker, R. *Chromatographic methods in clinical chemistry and toxicology*. John Wiley & Sons.
8. Weinberg, S. *Good laboratory practice regulations*. CRC Press.
9. Hirsch, A. F. *Good laboratory practice regulations*. Marcel Dekker.
10. ICH, USFDA & CDSCO Guidelines.

L= Lecture, T= Tutorial, P= Practical, C= Credit
^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA203T**
Course Title	**Quality Control and Quality Assurance**

Scope:
This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives:
At the completion of this subject it is expected that the student shall be able to know -
1. The cGMP aspects in a pharmaceutical industry.
2. To appreciate the importance of documentation.
3. To understand the scope of quality certifications applicable to Pharmaceutical industries.
4. To understand the responsibilities of QA & QC departments.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -
1. Understand the concepts of quality control, quality assurance, GMP, GLP.
2. Describe the various quality control guidelines by CDSCO, USFDA, EMEA, WHO etc.
3. Determine various quality requirements for drugs and finish products.

4. Report various quality related documents for pharmaceutical manufacturing along with quality certification.
5. Relate the importance of operations and controls in pharmaceutical manufacturing.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Concept and Evolution of Quality Control and Quality Assurance

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices:

Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

UNIT II **12 Hours**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering:

Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

UNIT III **12 Hours**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)

Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

UNIT IV **12 Hours**

Documentation in pharmaceutical industry:

Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

UNIT V **12 Hours**

Manufacturing operations and controls:

Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

Suggested Readings^: (Latest edition)

1. *Quality Assurance Guide by organization of Pharmaceutical Procedures of India*, Volume I & II, Mumbai.
2. Weinberg, S. *Good laboratory practice regulations*. CRC Press.
3. *World Health Organization. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection (Vol. 1 & 2)*. World Health Organization.
4. Sharma, P. P. *How to practice GMPs*. Vandana publication Pvt. Ltd Delhi.
5. *World Health Organization. The international pharmacopoeia (Vol. 1 to 5). General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms.* World Health Organization.
6. Hirsch, A. F. *Good laboratory practice regulations*. Marcel Dekker.
7. ICH guidelines
8. ISO 9000 and total quality management
9. Deshpande & Gandhi, N. *The drugs and cosmetics act 1940*. Susmit Publishers.
10. Shah D.H., QA *Manual. Business Horizons*.
11. Willig, S. H., & Stoker, J. R. *Good manufacturing practices for pharmaceuticals. A plan for total quality control. Drugs and the pharmaceutical sciences. Vol. 52*. Marcel Dekker Series.
12. Steinborn, L. *GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers,(Volume 1- With Checklists and Software Package)*. Taylor & Francis.
13. Sarker, D. K. *Quality Systems and Controls for Pharmaceuticals*. John Wiley & Sons.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPA204T**
Course Title	**Herbal and Cosmetic Analysis**

Scope:

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives:

At completion of this course student shall be able to understand -

1. Determination of herbal remedies and regulations.
2. Analysis of natural products and monographs.

3. Determination of Herbal drug-drug interaction.
4. Principles of performance evaluation of cosmetic products.

Course Learning Outcomes:

At the end of the course, students will be able to -

1. Understand the herbal drug regulations and standardization.
2. Identify the adulteration and deterioration of herbal drugs.
3. Analyze the natural products and adulterants.
4. Determine herbal drug-drug interaction.
5. Evaluate cosmetic products.

Syllabus: **Teaching hours: 60 Hours**

UNIT I **12 Hours**

Herbal remedies- Toxicity and Regulations:

Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues.

Herbal drug standardization:

WHO and AYUSH guidelines.

UNIT II **12 Hours**

Adulteration and Deterioration:

Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

Regulatory requirements for setting herbal drug industry:

Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

UNIT III **12 Hours**

Testing of natural products and drugs:

Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.

Monographs of Herbal drugs:

Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT IV **12 Hours**

Herbal drug-drug interaction:

WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

UNIT V **12 Hours**

Evaluation of cosmetic products:

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

Suggested Readings^: (Latest edition)

1. Evans, W. C. *Trease and Evans' Pharmacognosy*. Elsevier Health Sciences.
2. Kokate, C. K., Purohit, A. P., & Gokhale, S. B. *Pharmacognosy*. Nirali Prakashan, Pune.
3. World Health Organization. *Quality control methods for medicinal plant materials*. Geneva.
4. Kar, A. *Pharmacognosy and pharmacobiotechnology*. New Age International.
5. Ansari, S. H. *Essential of Pharmacognosy*, Birla publications Pvt. Ltd, New Delhi.
6. Sharma, P. P. *Cosmetics: Formulation, Manufacturing and Quality Control*. Vandana Publications Pvt Ltd. Delhi.
7. *Bureau of Indian Standards. Indian Standard Specification for Raw Materials*. New Delhi.
8. *Bureau of Indian Standards. Indian Standard Specification for 28 Finished Cosmetics*. New Delhi.
9. Harry, R. G. *Harry's cosmeticology*. Chemical Publishing Company.
10. Suppliers catalogue on specialized cosmetic excipients.
11. Butler, H. *Poucher's perfumes, cosmetics and soaps. Springer Science & Business Media.*
12. Barel, A. O., Paye, M., & Maibach, H. I. *Handbook of cosmetic science and technology*. CRC Press.
13. www.who.int
14. www.ayush.gov.in

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm - Pharmaceutical Analysis)
(Semester – II)

L	T	P	C
-	-	12	6

Course Code	**MPA205P**
Course Title	**Pharmaceutical Analysis Practical II**

Syllabus: **Teaching hours: 180 Hours**

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule.
2. Interpretation of organic compounds by FT-IR.

3. Interpretation of organic compounds by NMR.
4. Interpretation of organic compounds by MS.
5. Determination of purity by DSC in pharmaceuticals.
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra.
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams.
13. Quality control tests for Primary and secondary packing materials.
14. Assay of raw materials as per official monographs.
15. Testing of related and foreign substances in drugs and raw materials.
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil.
19. Determination of aryl amine content and Developer in hair dye.
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams).
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories.

L= Lecture, T= Tutorial, P= Practical, C= Credit

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme of (M. Pharm- Pharmaceutical Analysis)

Semester - III

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	-	-	1.0	-	-
2	MPA302T	Journal Club - I	1	-	-	1	-	-	1.0	-	-
3	MPA303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MPA304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	**7**	**28**		**21**					
			35								

Semester - IV

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MPA401T	Journal Club - II	1	-	-	1	-	-	1.0	-	-
2	MPA402P	Research work and Colloquium	-	31	-	16	-	1.0		1.0	-
3	MPA403T	Discussion/Final Presentation	3	-	-	3	-	-	1.0	-	-
		Total	**4**	**31**		**20**					
			35								

*** Non University Examination (NUE)**

L: *Lectures, P/T: Practicals/Tutorial, C: Credits*

LPW: *Laboratory / Project Work*

SEE: *Semester End Examination*

CE: *Continuous Evaluation*

w.e.f. academic year 2018-2019 and onwards

NIRMA UNIVERSITY
Institute of Pharmacy

(M. Pharm)
(Semester - III)

L	T	P	C
4	-	-	4

Course Code	MRM301T
Course Title	Research Methodology & Biostatistics

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. List various types of research and significance of review of literature
2. Describe the parametric and non- parametric tests related to biostatistics
3. Discuss various types of medical research
4. Explain CPCSEA guidelines for laboratory animal facility
5. Express the role of declaration of Helsinki

Syllabus: **Teaching hours: 60 Hours**

UNIT I **15 Hours**

General Research Methodology: Research, objective, protocol design, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding and related labelling techniques, conduct, monitoring, analysis and interpretation, reporting and record keeping, Scientific writing.

UNIT II **20 Hours**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values, application based case studies.

UNIT III **10 Hours**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT IV **05 Hours**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals, Import of animals.

UNIT V **10 Hours**

General Guidelines of clinical research, ICH E9 guidelines, Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Suggested Readings^: (Latest Edition)

1. Best, J.W., Kahn, J.V., *Research In Education*. New Delhi, Prentice Hall of India Pvt. Ltd.
2. Halton, M., *Presentation Skills*. Indian Society for Institute Education
3. Mcfarlane, G., *A Practical Introduction to Copyright*. McGraw Hill
4. Davis, R.M., *Thesis Projects in Science and Engineering*. St. Martin's Press.
5. Anderson, J., *Thesis and Assignment Writing*. John Wiley & Sons.

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^ this is not an exhaustive list