Programme : B.Pharmacy

Sl. No.	Course / Code	Gender	Environment and Sustainability	Human Values	Professional Ethics
01	Pharmaceutical Analysis **(BP 102T)**			• Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures • Pharmacopoeia, sources of impurities in medicinal agents, limit tests	•
02	Pharmaceutics-1 **(BP 103T)**	Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area	•	• Handling of Prescription and Errors in prescription	•
03	Pharmaceutical inorganic chemistry **(BP 104T)**		• Radio activity, Measurement of radioactivity, properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes – Sodium iodide I^{131}, Storage conditions, precautions and pharmaceutical application of radioactive substances.	• History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate.	•
04	Remedial Biology **(BP 106RBT)**	• Parts of female reproductive system • Parts of male reproductive system • Spermatogenesis and Oogenesis • Menstrual cycle	•	• Definition and characters of living organisms • Diversity in the living world • Binomial nomenclature • Five kingdoms of life and basis of classifications. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus	•
	Remedial Biology **(BP 112RBP)**		•	•	• Determination of blood group • Determination of blood pressure • Determination of tidal volume
	Remedial		•	•	• Application in solving

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	Mathematics **(BP 106 RMT)**				chemical kinetics and pharmacokinetics equations.
	Human anatomy and physiology-II **(BP 201T)**	• Anatomy of male and female reproductive system, functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition	•	•	• Formation and role of ATP, Creatinine Phosphate and BMR • Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance
	Human anatomy and physiology **(BP 207P)**		•	• Determination of tidal volume and vital capacity • Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens • Recording of basal mass index	• Study of family planning devices and pregnancy diagnosis test • Demonstration of total blood count by cell analyser • Permanent slides of vital organs and gonads
	Biochemistry **(BP 203T)**		•	•	• Biological significances of ATP and cyclic AMP • Hormonal regulation of blood glucose level and Diabetes mellitus
	BIOCHEMISTRY **(BP 209P)**		•	•	• Determination of blood creatinine • Determination of blood sugar • Determination of serum total cholesterol
	Pathophysiology **(BP 204T)**		•	• Asthma, Chronic obstructive airways diseases • Acute and chronic renal failure • Diabetes, Disorders of sex hormones	• Pathophysiology of Atherosclerosis • Meningitis, Typhoid, Leprosy, Tuberculosis • AIDS, Syphilis, Gonorrhea
	Computer applications in pharmacy		•	•	• Pharmacy Drug database • Patient Monitoring system, Pharma

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	(BP 205T)				information system • Impact of Bioinformatics in Vaccine Discovery • Chromatographic data analysis (CDS), Laboratory Information management system (LIMS) and text information management system (TIMS)
	Computer applications in pharmacy **(BP 205P)**		•	•	• Design a form in MS Access to view, add, delete and modify the patient record in the database.
	Pharmaceutical organic chemistry-II **(BP 301T)**		•	•	• Analytical constants-Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determinations
	Pharmaceutical organic chemistry-II **(BP 301P)**		•	•	• Acid value • Saponification value • Iodine value
	Pharmaceutical Microbiology **(BP 303T)**	Study of morphology, classification, reproduction / replication and cultivation of Fungi and Viruses	•	•	• Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP • Assessment of a new antibiotic • Appliciton of cell cultures in pharmaceutical industry and research
	Pharmaceutical Microbiology **(BP 303P)**		•	•	• Microbiological assay of antibiotics by cup plate method and other methods • Sterility testing of

					• pharmaceuticals • Bacteriological analysis of water • Biochemical test
	Pharmaceutical Engineering **(BP 304T)**		• Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic and metals, basic of material handling systems.	•	•
	Pharmaceutical Organic Chemistry-III **(BP 401T)**		•	•	• Stereospecific and stereoselective reactions
	Medicinal Chemistry-I **(BP 406P)**		•	•	• Determination of partition coefficient for any two drugs
	Physical Pharmaceutics-II **(BP 403T)**		• Reaction kinetics : Zero, pseudo-zero, first & second order, units of basic rate constnts, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific and general acid base catalysis, simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis and oxidation.	•	• Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention.

	Physical pharmaceutics-II **(BP 407P)**		•	•	• Accelerated stability studies
	Pharmacology **(BP 404T)**		•	• Addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy. • Adverse drug reactions, . • Drug interactions (pharmacokinetic and pharmacodynamic) • Drug discovery and clinical evaluation of new drugs-drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance • Alcohols and disulfiram • Drug addiction, drug abuse, tolerance and dependence	•
	Pharmacology-I **(BP 408P)**		• Maintenance of laboratory animals as per CPCSEA guidelines	•	•
	Pharmacognosy and Phytochemistry-I **(BP 405T)**		• Definition, history, scope and development of pharmacognosy	• Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties. • Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.	• Edible vaccines • Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine. • Novel medicinal agents from marine sources
	Pharmacognosy and Phytochemistry-I **(BP 408P)**		•	•	• Determination of Fiber length and width • Determination of number of starch grains by Lycopodium spore method • Determination of Ash value • Determination of Extractive values of

					crude drugs • Determination of moisture content of crude drugs • Determination of swelling index and foaming
	Medicinal Chemistry-II **(BP 501T)**	• Nomenclature, stereochemistry and metabolism of steroids • Testosterone, Nandralone, progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol. • Sildenafil, Tadalafil • Mifepristone, Norgestril, Levonorgestrol • Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone	•	•	•
	Industrial Pharmacy-I **(BP 502T)**		• Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms. • Stability studies • Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality	•	•

			control tests.		
	Industrial Pharmacy-I **(BP 506P)**		•	•	• Preformulations studies on paracetamol/asparin/or any other drug • Preparation and evaluation of Paracetamol tablets • Preparaton and evaluation of Aspirin tablets • Coating of tablets-film coating of tables/granules • Preparation and evaluation of Tetracycline capsules • Preparation of calcium Gluconate injection • Preparation of Ascorbic acid injection • Quality control test of (as per IP) marketed tablets and capsules • Preparaton of Eye drops/and Eye ointments • Preparation of Creams (Cold/vanishing cream) • Evaluation of Glass containers (as per IP)
	Pharmacology-II **(BP 503T)**	• Androgens and anabolic steroids • Estrogens, progesterone and oral contraceptives • Drugs acting on the uterus	•	•	• Principles and applications of bioassay • Types of bioassay • Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT.
	Pharmacognosy and Phytochemistry-II **(BP 504T)**		• Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.	•	•
	Pharmaceutical Jurisprudence	Objectives, Definitions, institutional animal	•	•	• A brief review, introduction, study of

	(BP 505T)	ethics committee, CPCSEA guidelines for Breeding and stocking of animals, performance of experiments, transfer and acquisition of animals for experiment, records, power to suspend or revoke registration, offences and penalities			drugs enquiry committee, health survey and development committee, Hathi committee and mudaliar committee • Definition, pharmacist in relation to his job, trade, medical profession and his profession, pharmacist's oath • Right to information Act.
	Medicinal Chemistry-III **(BP 601T)**		•	•	• Concept and applications of combinatorial chemistry : solid phase and solution phase synthesis.
	Medicinal Chemistry_III **(BP 607P)**	Preparation of medicinally important compounds or intermediates by Microwave irradiation technique	•	•	•
	Herbal drug technology **(BP 603T)**		• Herbal drugs industry: Present scope and future prospects • A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.	•	• Good manufacturing practices (GMP), patenting and regulatory issues of herbal drugs. • Conventional herbal formulations like syrups, mixtures and tablets and novel dosage forms like pytosomes. • WHO and ICH guidelines for the assessment of herbal drugs stability testing of herbal drugs. • Definition of the terms : Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy • Patenting aspects of traditional knowledge and natural products. Case study of Curcuma and Neem

					• Regulations in India (ASU, DTAB, ASU, DCC), Regulation of manufacture of ASU drugs – Schedule Z of drugs and cosmetics act for ASU drugs.
	Biopharmaceutics and Pharmacokinetics **(BP 604T)**	Factors influencing drug absorption	•	•	•
	Pharmaceutical Biotechnology **(BP 605T)**		•	•	• Biosensors-Working and applications of biosensors in pharmaceutical industries • Brief introduction of PCR • General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxine, serum-immune blood derivatives and other products relative to immunity • Immuno blotting techniques-ELISA, Western blotting, southern blotting
	Pharmaceutical Quality Assurance **(BP 606T)**		• Personnel responsibilities, training hygiene and personal records. • Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. • Equipment selection, purchase, specification, maintenance, purchase	•	• Definition and concept of Quality control, quality assurance and GMP • Definition, elements, philosophies, • Purpose, participants, process of harmonization, brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines • Definition, Overviw, elements of QbD program, tools • Overview, benefits,

			specifications and maintenance of stores for raw materials.		elements steps for registration • Principles and procedures.
	Industrial Pharmacy-II **(BP 702T)**		• Space requirements, raw materials, pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentations, SUPAC guidelines, introduction to platform technology	• Personnel requirements	• WHO guidelines for technology transfer (TT) : Terminology, technology transfer protocol, quality risk management, transfer from R & D to production (Process, packaging and cleaning), Granularity of TT process (API, Excipients, finished products, packaging materials) Documentation, premises and equipments, qualification and validation, quality control, analytical method transfer, approved regulatory bodies and agencies, Commercialization – practical aspects and problems (case studies), TT agencies in India- APCTD, NRDC, TIFAC,BCIL, TBSE/ SIDBI; TT relted documentation – confidentiality agreement, licensing, MoUs legal issues • Introduction Historical overview of regulatory affairs, regulatory authorities, role of regulatory affairs department, responsibility of regulatory affairs professionals. • Drug development teams, Non-clinical drug

					development, pharmacology, drug metabolism and toxicology, General consideration of investigational new drug (IND) application, investigator's brochure (IB) and New Drug application (NDA), Clinical research/BE studies, Clinical research protocols, Biostatistics in Pharmaceutical product development, data presentation for FDA submissions, management of clinical studies. • Quality management and certificaqtions: Concept of quality, totl quality management, qualityby design (QbD), Six sigma concept, out of specifications (OOS), change control, introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP • Central drug standard control organization (CDSCO) and state licensing authority: Organization, Responsibilities, certificate of Pharmaceutical product (COPP), Regulatory requirements and approval procedures for New Drugs.
	Pharmacy Practice **(BP 703T)**		•	• Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals,	•

				• Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions. • Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management. • Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store. • Financial, materials, staff, and infrastructure requirements.	
	Novel Drug Delivery systems **(BP 704T)**		•	•	• Definition, advantages and disadvantages, microspheres/microcaps ules, microparticles, methods of microencapsulation, applications • Introduction, Principles of bioadhesion/ mucoadhesion, concepts, advantages and

					disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems •
	Social and Preventive Pharmacy **(BP 802T)**		•	• Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. • Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. • Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health • personal hygiene and health care; avoidable habits • General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse • HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio	•

					the Market; Role of market research. • Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry. • Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products. • Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management. • Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR. • Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in

				programme. • National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program • Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.	
	Pharma Marketing Management **(BP 803ET)**		•	•	• Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior. • Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing

					price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority). • Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.
	Pharmaceutical Regulatory Science **(BP 804ET)**		•	•	• Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development. • Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. • Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications) • Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common

					Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research • Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials • Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book
	Pharmacovigilance **(BP 805T)**		•	• History and development of Pharmacovigilance • Importance of safety monitoring of Medicine • WHO international drug monitoring programme • Pharmacovigilance Program of India(PvPI) • Definitions and classification of ADRs • Detection and reporting • Methods in Causality assessment • Severity and seriousness assessment • Predictability and preventability assessment • Management of adverse drug reactions	• Anatomical, therapeutic and chemical classification of drugs • International classification of diseases • Daily defined doses • International Non proprietary Names for drugs • WHO adverse reaction terminologies • MedDRA and Standardised MedDRA queries • WHO drug dictionary • Eudravigilance medicinal product dictionary • Basic drug information resources • Specialised resources for

				• Terminologies of adverse medication related events • Regulatory terminologies • Vaccine Pharmacovigilance • Vaccination failure • Adverse events following immunization • Passive surveillance – Spontaneous reports and case series • Stimulated reporting • Active surveillance – Sentinel sites, drug event monitoring and registries • Comparative observational studies – Cross sectional study, case control study and cohort study • Targeted clinical investigations • Effective communication in Pharmacovigilance • Communication in Drug Safety Crisis management • Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	ADRs • Establishing in a hospital • Establishment & operation of drug safety department in industry • Contract Research Organisations (CROs) • Establishing a national programme • Pre clinical phase • Clinical phase • Post approval phase (PMS) • Organization and objectives of ICH • Expedited reporting • Individual case safety reports • Periodic safety update reports • Post approval expedited reporting • Pharmacovigilance planning • Good clinical practice in pharmacovigilance studies • Genetics related ADR with example focusing PK parameters. • Paediatrics • Pregnancy and lactation • Geriatrics • CIOMS Working Groups • CIOMS Form • D&C Act and Schedule Y • Differences in Indian and global pharmacovigilance requirements •
	Quality control and standardization of		• Stability testing of herbal medicines.Application	• Basic tests for drugs – Pharmaceutical substances, Medicinal	

					metabolism, lead discovery based on clinical observation. • Bioisosterism, Classification, Bioisosteric replacement. Any three case studies • SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA. • Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, • Rigid docking, flexible docking, manual docking, • Docking based screening. *De novo* drug design. • Introduction to Bioinformatics, chemoinformatics. ADME databases, • chemical, biochemical and pharmaceutical databases. • Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods

	herbals **(BP 806ET)**		of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.		plants materials and dosage forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use • cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants. • EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines • Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems • Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products
	Computer aided drug design **(BP 807 ET)**		•	•	• Stages of drug discovery and development • Rational approaches to lead discovery based on traditional medicine, • Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug

					and Conformational Analysis, global conformational minima determination.
	Cell and Molecular biology (Elective Subject) **(BP 808ET)**	a) Cell and Molecular Biology: Definitions theory and basics and Applications. b) Cell and Molecular Biology: History and Summation. c) Properties of cells and cell membrane. d) Prokaryotic versus Eukaryotic e) Cellular Reproduction Chemical Foundations – an Introduction and Reactions (Types)	•	•	•
	Cosmetic Science **(BP 809ET)**		•	•	• Classification of cosmetic and cosmeceutical products Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs • Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application. • Basic structure and function of skin. • Basic structure of hair. Hair growth cycle. • Common problems associated with teeth and gums. • Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.

					Application of these products in formulation of cosmeceuticals. • Actives & mechanism of action. • Conditioning shampoo, Hair conditioner, anti-dandruff shampoo, • Hair oil. Chemistry and formulation of Para-phylene diamine based hair dyes. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth, Teeth whitening, Mouthwash. • Sun protection, Classification of Sunscreens and SPF. • Skin care: Aloe and turmeric. • Hair care: Henna and amla. • Oral care: Neem and clove. • BIS specification and analytical methods for shampoo, skincream and toothpaste. • Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evaluation and skin benefits. • Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic,

					dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes. • Cosmetic problems associated with skin: Blemishes, wrinkles, acne, prickly heat and body odor. Antiperspirants and Deodorants- Actives and mechanism of action.
	Pharmacological Screening Methods **(BP 810ET)**		•	• Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. • Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia. • a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. • b. Diuretics, nootropics, anti-Parkinson's,antiasthmatics, • Preclinical screening models: for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's	• Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data

				disease • Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal • muscle relaxants, drugs acting on eye, local anaethetics • Preclinical screening models: for CVS activity- antihypertensives, • diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
	Advanced instrumentation techniques **(BP 811ET)**		• Importance, various components, Principle, different methods, Limitation	•	• Calibration and validation-as per ICH and USFDA guidelines • Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC
	Dietary supplements and nutraceuticals **(BP 812ET)**		•	•	a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals. b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. c) Pharmacopoeial

					Specifications for dietary supplements and nutraceuticals.
	Elective course on pharmaceutical products development		•	•	• Optimization techniques in pharmaceutical product development.A study of various optimization techniques for pharmaceutical product development with specific examples.Optimization by factorial designs and their applications.A study of QbD and its application in pharmaceutical product development. • Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

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Programme : M.Pharmacy-PHARMACEUTICS

Sl. No.	Course / Code	Gender	Environment and Sustainability	Human Values	Professional Ethics
01	Drug Delivery Systems **(MPH 102T)**			• Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	•
	Modern Pharmaceutics **(MPH 103T)**			•	• **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. • **cGMP & 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 (TQM). • **Study of consolidation parameters:** Diffusion parameters, dissolution rate test parameters and pharmacokinetic parameters, Heckel plots, similarity factor and difference factor– f_2 and f_1, Higuchi and Peppas plot, linearity, concept of significance, standard deviation, Chi square test, students t-test, ANOVA test.
	Regulatory Affairs **(MPH 104T)**			• **Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee formation and working procedures, informed Consent process and procedures. HIPAA-new requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	• **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), *In-vitro* drug product performance, ANDA regulatory approval

					process, NDA approval process, BE and *In-vivo* drug product assessment, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. • **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs, ways and means of US registration for foreign drugs. • CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and e-CTD format, Industry and FDA liasion. Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. • **Non clinical drug development:** Global submission of INDA, NDA, ANDA. Investigation of Medicinal Products Dossier (IMPD) and Investigator Brochure (IB).
	Advanced Biopharmaceutics & Pharmacokinetics **(MPH 202T)**			•	• **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. Biopharmaceutical classification system, methods. Permeability: *In-vitro*, *in-situ* and *In-vivo*methods. generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.
	Computer aided drug development **(MPH 203T)**			•	1. **a. 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,

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Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

- **b.Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

2. **Computational Modeling of Drug Disposition:** Introduction to 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.
3. **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

4. **a. 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 (IVIVC), biowaiver considerations

   b. Computer simulations in pharmacokinetics and pharmacodynamics: introduction, computer simulation whole organism, isolated tissues, organs, cell, proteins and genes.

   c. Computers in clinical development: Clinical data collection and management,

					regulation of computer systems. 5. **Artificial intelligence (AI), robotics and computational fluid dynamics:** General overview, pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. current challenges and future directions.

Programme : M.Pharmacy-PHARMACEUTICAL ANALYSIS

Sl. No.	Course / Code	Gender	Environment and Sustainability	Human Values	Professional Ethics
01	Advanced Pharmaceutical Analysis **(MPA 102T)**		**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. **Impurity profiling and degradent characterization:** Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing		• **Biological tests and assays of the following:** a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

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			guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis on photostability testing guidelines, ICH stability guidelines for biological products **Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.		• 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.
	Pharmaceutical Validation **(MPA 103T)**			•	**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. **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 **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 of 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.
	Food Analysis **(MPA 104T)**		**Pesticide analysis:** Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.	•	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.

			Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.		
	Modern Bio-Analytical Techniques **(MPA 202T)**			•	**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. **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.
	Quality control and quality assurance **(MPA 203T)**			•	**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. **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.
	Herbal and cosmetic analysis **(MPA 204T)**		**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	•	**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

			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.		examples. Challenges in monitoring the safety of herbal medicines.

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Programme : M.Pharmacy-PHARMACEUTICAL REGULATORY AFFAIRS

Sl. No.	Course / Code	Gender	Environment and Sustainability	Human Values	Professional Ethics
01	Good Regulatory Practices **(MRA 101T)**		• Customers, Returns • Stability testing principles,	•	**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. **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 **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. **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 **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.
	Documentation and Regulatory Writing **(MRA 102T)**				**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). **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. **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.

					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). **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
	Clinical Research Regulations **(MRA 103T)**			1. 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 Clinical Research Related Guidelines	**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

				* 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, * E11 – Clinical Investigation of Medicinal Products in the Pediatric Population * General biostatics principle applied in clinical research	**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) 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
	REGULATIONS AND		**Intellectual Property**	Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices,

	LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS **(MRA 104T)**		**Rights:** Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	(with latest amendments): 1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA 2. 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. •	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 • Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards 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
	Regulatory Aspects of drugs & Cosmetics **(MRA 201T)**			•	**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.

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.

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

Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, 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)

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.
	Regulatory Aspects of Herbal and Biologicals **(MRA 202T)**			• **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) • **Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union.	**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. **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 **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
	Regulatory aspects of Medical devices **(MRA 203T)**			•	**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). **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 **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. **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. **ASEAN, China & Japan:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.

					IMDRF study groups and guidance documents.
	Regulatory aspects of food and nutraceuticals **(MRA 204T)**			•	**Nutraceuticals:** Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market. **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. **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. **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 **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.

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Programme : M.Pharmacy-PHARMACOLOGY

Sl. No.	Course / Code	Gender	Environment and Sustainability	Human Values	Professional Ethics
	Pharmacological and Toxicological screening methods-1 **(MPL 103T)**			**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	**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, antidiarrheal and laxatives. Preclinical screening of new substances for the pharmacological activity using *in-vivo, in-vitro*, and other possible animal alternative models. **Cardiovascular Pharmacology:** antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents, Anti cancer agents, Hepatoprotective screening methods. 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
	Advanced Pharmacology-II **(MPL 201T)**				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
	Pharmacological and Toxicological Screening methods-II **(MPL 202T)**	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			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 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 Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.
	Principles of drug discovery **(MPL 203T)**				**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.

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

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, 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.

- 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
	Clinical research and pharma-covigilance **(MPL 204T)**			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 centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	**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 **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 • 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. 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. • Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

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Programme : PHARM.D

Course/Code	Gender	Environment and sustainability	Human Values	Professional ethics
Human Anatomy and Physiology **(1.1 T)**	Reproductive system 1.Male and female reproductive system 2.Their hormones – Physiology of menstruation 3.Spermatogenesis & Oogenesis 4.Sex determination (genetic basis) 5.Pregnancy and maintenance and parturition 6.Contraceptive devices			Drugs and athletics
Human Anatomy and Physiology **(1.1 P)**	1. Reproductive system. 2. To perform pregnancy diagnosis test.			
Pharmaceutics **(1.2 T)**			Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.	1.Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief 2.Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

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Pharmaceutics **(1.2 P)**			Incompatibilities a.Mixtures with Physical b.Chemical & Therapeutic incompatibilities * colourless bottles required for dispensing Paper envelope (white), butter paper and white paper required for dispensing.	
Medicinal Biochemistry **(1.3T)**				1. Introduction to clinical chemistry: Cell; composition; malfunction; Roll of the clinical chemistry laboratory. 2.The kidney function tests : Role of kidney; Laboratory tests for normal function includes- a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.) b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid) c) Urine \concentration tested) Urinary tract calculi. (stones) 3. Liver function tests : Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation. a) Test for hepatic dysfunction - Bile pigments metabolism. b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.

				c) Dye tests of excretory function. d) Tests based upon abnormalities of serum proteins. Selected enzyme tests. 4. Lipid profile tests : Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
Pharmaceutical Inorganic Chemistry **(1.5 T)**		• Dental Products • Radio Pharmaceutics	Errors	
Pathophysiology **(2.1T)**			1.Chemical Mediators of inflammation 2.Drug Hypersensitivity 3.Cigarette smoking & its ill effects 4.Biological Effects of Radiation 5.Etiology and hazards of obesity 6.Complications of diabetes 7.Diagnosis of cancer 8.Disorders of vitamins 9.Methods in Pathology-Laboratory values of clinical significance 10.Pathophysiology of Dengue Hemorrhagic Fever (DHF)	Cancer:differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
Pharmaceutical Microbiology **(2.2T)**			Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.	1.Disinfectants- Study of disinfectants , antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations. 2.Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.

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Pharmaceutical Microbiology **(2.2P)**			Diagnostic tests for some common diseases, Widal, malarial parasite.** * Indicate minor experiment & ** indicate major experiment	
Pharmacognosy & Phytopharmacuticals **(2.3T)**			Different methods of adulteration of crude drugs.	
Pharmacology-I **(2.4T)**			1.Pre-clinical evaluations 2.Drug interactions	
Community Pharmacy **(2.5T)**			1.Definition, scope of community pharmacy Roles and responsibilities of Community pharmacist 2.Prescriptions – parts of prescription, legality & identification of medication related problems like drug interactions. 3.Patient medication adherence Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence. 4.Health screening services Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing *5.OTC Medication- Definition, OTC medication list & Counselling* 5.Health Education: WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients. *Commonly occurring Communicable Diseases,causative agents, Clinical presentations and	1.Community Pharmacy Management a) Selection of site, Space layout, and design b)Staff, Materials- coding, stocking c) Legal requirements d) Maintenance of various registers e) Use of Computers: Business and health care soft wares 2.Pharmaceutical care Definition and Principles of Pharmaceutical care. 3.Patient counselling Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design & layouts, advisory labels

			prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS *Balance diet and treatment & prevention of deficiency disorders Family planning – role of pharmacist 6.Code of ethics for community pharmacists	
Paramacology-II **(3.1T)**				Recombinant DNA technology: principles. Processes (gene transfer technology) and applications
Pharmaceutical Analysis **(3.2T)**				1. GLP, ISO 9000. 2.Total quality management, quality review and documentation. 3.ICH-international conference for harmonization-guidelines. 4.Regulatory control.
Pharmacotherapeutics-II **(3.3T)**			Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis,Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection-Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis	
Pharmaceutical Jurisprudence **(3.4T)**		Drugs and Cosmetics Act, 1940 and its rules 1945 : Objectives, Legal definition, Study of Schedule's with reference to Schedule B,	1.Medicinal and Toilet Preparation Act –1955: Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations. 2.Drug Price control Order & National Drug Policy (Current).	1.Pharmaceutical Legislations – A brief review. 2. Principle and significance of professional ethics. Criticql study of the code of pharmaceutical ethics drafted by PCI.

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		C & C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y. Sales, Import, labeling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems.	3.Prevention of Cruelty to animals Act-1960. 4.Patents & design Act-1970. 5.Brief study of prescription and Non-prescription Products.	
Medicinal Chemistry **(3.5T)**				Diagnostic agents:
Pharmaceutical Formulation **(3.6T)**				1.Pharmaceutical dosage form - concept and classification 2. Tablets: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
Pharmacotherapeutics-III **(4.1P)**			Psychiatry disorders : Schizophrenia, Affective disorders, Anxiety disorders, sleep disorders, Obsessive compulsive disorders	
Hospital Pharmacy **(4.2T)**		*1.Continuing professional development programs* Education and training 2.Radio Pharmaceuticals – Handling and	*1.Hospital pharmacy-Organisation and management* a) Organizational structure-Staff, Infrastructure & work load statistics b) Management of materials and finance c) Roles & responsibilities of hospital pharmacist *2.Hospital pharmacy services*	*1.Hospital drug policy* a) Pharmacy and Therapeutic committee (PTC) b) Hospital formulary c) Hospital committees - Infection committee - Research and ethical committee d) developing therapeutic

		packaging	a) Procurement & warehousing of drugs and Pharmaceuticals b) Inventory control Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock c) Drug distribution in the hospital i) Individual prescription method ii) Floor stock method iii) Unit dose drug distribution method d) Distribution of Narcotic and other controlled substances e) Central sterile supply services – Role of pharmacist	guidelines e) Hospital pharmacy communication – Newsletter *2. Manufacture of Pharmaceutical preparations* a) Sterile formulations – large and small volume parenterals b) Manufacture of Ointments, Liquids, and creams c) Manufacturing of Tablets, granules, capsules, and powders d) Total parenteral nutrition
Hospital Pharmacy **(4.2P)**				1.Pharmacy and Therapeutics committee – Organization, functions, 2. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.
Clinical Pharmacy **(4.3T)**			1.Patient data analysis The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices. 2.Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results a. Haematological, Liver function, Renal function, thyroid function tests b. Tests associated with cardiac disorders c. Fluid and electrolyte balance d. Microbiological culture sensitivity tests	1.Definitions, development and scope of clinical pharmacy 2. Introduction to daily activities of a clinical pharmacist a. Drug therapy monitoring (medication chart review, clinical b. Ward round participation c. Adverse drug reaction management d. Drug information and poisons information e. Medication history f. Patient counseling g. Drug utilisation evaluation (DUE) and review (DUR) h. Quality assurance of clinical pharmacy

			e. Pulmonary Function Tests 3.Drug & Poison information a. Introduction to drug information resources available b. Systematic approach in answering DI queries c. Critical evaluation of drug information and literature d. Preparation of written and verbal reports e. Establishing a Drug Information Centre f. Poisons information- organization & information resources	services 3.Pharmacovigilance a. Scope, definition and aims of pharmacovigilance b. Adverse drug reactions - Classification, mechanism, c. Reporting, evaluation, monitoring, preventing & management of ADRs d. Role of pharmacist in management of ADR. 7.Communication skills, including patient counselling techniques, 8.Pharmaceutical care concepts 9.Critical evaluation of biomedical literature 10.Medication errors
Clinical Pharmacy **(4.3P)**				a. Answering drug information questions (4 Nos) b. Patient medication counselling (4 Nos) c. Case studies related to laboratory investigations (4 Nos) d. Patient medication history interview (3 Nos)

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