SPECIALIZATION WISE SYLLABUS FOR PhD ENTRANCE EXAMINATION IN PHARMACEUTICAL SCIENCES (2018)

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SPECIALIZATION: PHARMACEUTICS

I. PRODUCT DEVELOPMENT AND PACKAGING TECHNOLOGY

1. Preformulation Studies: Study of physical, chemical and pharmaceutical factors influencing formulation of drugs
2. Study of different types of formulation additives: diluents, binders, disintegrators, Lubricants, vehicles, antioxidants, preservatives, colouring, flavouring, sweetening, suspending and emulsifying agents, materials for an ointment and suppository bases, drug excipient interaction and incompatibilities
3. Formulation Considerations: Technology involved, detailed study of equipment (machines) employed along with layouts, problems to be encountered and evaluation of
   - **a)** Solid dosage forms – Tablets, tablet coatings, capsules
   - **b)** Liquid dosage forms – Liquid orals including solutions, suspensions, elixirs, syrups, and emulsions
   - **c)** Semisolid dosage forms – Ointments, creams, suppositories
   - **d)** Sterile dosage forms – Parenteral and ophthalmic
   - **e)** Aerosols
   - **f)** Herbal cosmetics
   - **g)** Designing of fast-release products
4. Kinetic principles and stability testing: Order of reaction, stability study programmes for formulations, determination of expiry date (shelf life), and overages calculations, stability indicating assays, physical stability testing
5. Polymers: Classification, general methods of synthesis, properties characterization and evaluation, biodegradable polymers, classification, mechanism of biodegradation in the body, pharmaceutical applications of polymers
6. Theory of dissolution: Design of dissolution apparatus, dissolution media, dissolution rate testing, release rate constant, dissolution rate data handling
7. Optimization techniques: Concept of optimization, optimization parameters, classical optimization, statistical design and optimization methods
8. Packaging:
   - **a)** New concepts in pharmaceutical packaging, package systems, package design research, packaging materials with special reference to polymers, metals, glass and plastics, control of packing materials
   - **b)** Blister and strip packaging, testing of containers & closures
   - **c)** Pharmacopoeial tests and specifications, defects in packages, stability of package and packaging material
   - **d)** Ancillary materials used in packaging, sterilization of packaging materials
   - **e)** packaging of parenteral, ophthalmic and aerosols, corrugated fibre board materials, label and leaflets preparation, legal requirements

II. BIOPHARMACEUTICS / PHARMACOKINETICS AND NOVEL DRUG DELIVERY SYSTEMS

1. Pharmacokinetic models: One and two compartment models, pharmacokinetic parameters, absorption rate constant, biological half-life, apparent vo0lume of distribution, renal clearance, total body clearance, pharmacokinetics of multiple dosing, dosage regimen design, loading and maintenance doses, kinetics of sustained-release and continuous blood levels
2. Bioavailability and bioequivalence: Objective, significance and factors affecting bioavailability and bio equivalence, study design and assessment methods for bioavailability and bioequivalence, correlation of in vitro dissolution with in vivo bioavailability. statistical concepts in estimation of bioavailability and bioequivalence, regulatory requirements
3. Controlled drug delivery system: Theory of controlled release drug delivery systems, release and diffusion of drugs from CDDS, general methods of design and evaluation of CDDS, carriers for drug delivery systems, prodrugs, physical, chemical and biomedical engineering approach to achieve controlled drug delivery
4. Microencapsulation: Methods, kinetics of drug release from microcapsules, technology and applications
5. Transdermal drug delivery systems: Theory, formulation and evaluation, iontophoresis
6. Implants and inserts: Types, design and evaluation methods
7. Osmotically regulated systems: General considerations, classification and development of osmotic pumps, applications
8. Targeted drug delivery system: Concept of drug targeting and its importance in therapeutics, methods in drug targeting, drug immobilization techniques, nanoparticles, liposomes, niosomes, pharmacosomes and resealed erythrocytes, dendrimers, multiple emulsions
9. Advanced concepts in the design, developmentand production of sustained-release products
10. Present status and scope of biotechnology in pharmacy: Production and applications of monoclonal antibodies, fermentation, characterization and optimization of fermentation processes, types, design and operation of fermenters

III. DRA, INTELLECTUAL PROPERTY RIGHTS & QUALITY ASSURANCE

1. Requirements of GMP, CGMP, GLP, USFD, WHO guidelines and ISO 9000 series, Drugs and cosmetics act and rules
2. Documentation: Protocols, forms and maintenance of records in pharmaceutical industry preparation of documents for new drug approval and export registration, patent processing, and its applications
3. Pharmaceutical process validation: Concepts in validation, validation of manufacturing and analytical equipment, process validation in manufacturing dosage formulations, applications of process validation
4. Pilot plant scale up Techniques, transfer of technology from R&D to pilot scale and plant scale
5. Basic concepts of quality control and quality assurance systems, source and control of quality variation of raw materials, containers, closures, personnel, environment, etc.
6. In process quality control tests, IPQC problems in Pharmaceutical industries, ICH guidelines
7. Sampling plans, sampling and characteristic curves
8. Mater formula generation and maintenance, standard operating procedure (SOP) for different dosage forms
9. New product launch and trouble shooting in production
10. Clinical trials and toxicological evaluation of drugs
11. Sewage disposal and pollution control

SPECIALIZATION: PHARMACEUTICAL CHEMISTRY

I. DRUG DESIGN INCLUDING ORGANIC NAME REACTIONS

1. Physicochemical properties in relation to drug action, metabolic transformation of drugs and its role in development of new drug molecules, metabolic antagonism
2. Stereochemical aspects of drug receptor interactions and mechanism of drug interaction, isosterism and bioisosterism as guides to structural variations, concepts of conformational analysis and its role in design and development of new drug molecules
3. Principles of drug design, analogue synthesis versus rational design, discovery of lead compounds, pharmacophoric identification, prodrugs and soft drug
4. QSAR and introduction to molecular modelling
5. In organic chemistry, the following name reactions and molecular rearrangements will be discussed in detail with reference to their application in the synthesis of some medicinal agents, where possible:
   - **a)** Claisen- Schmidt reaction e.g. Sulfisoxazole
   - **b)** Perkins reaction e.g. sulinadac
   - **c)** Friedal Craft reaction
   - **d)** Aldol condensation
   - **e)** Mannich reactions e.g. Tolmetin, Atropine, Ethacrynic acid
   - **f)** Beckmann's rearrangement.
   - **g)** Wagner-Meerwein rearrangement
   - **h)** Wittig reaction
   - **i)** Oppenaur oxidation.
   - **j)** (Meervein- pondroff-verley) M.P.V. reduction

II. CHEMISTRY OF NATURAL PRODUCTS

1. Natural products as a Lead for new pharmaceutical
2. The natural products obtained from terrestrial and microbial sources will be discussed in the light of various degradative and synthetic approaches supported by spectral data. Important members representing the following classes of natural products shall be discussed:
   - **a)** Alkaloids: General introduction and classification, isolation and purification methods, general methods employed for determining the structure of alkaloids, constitution of morphine, reserpine and quinine
   - **b)** Steroids: General introduction, stereochemistry, nomenclature and structure elucidation of sterols (cholesterol), sapogenin (diosgenin) and cardiac glycosides
   - **c)** Amino acids, peptides and nucleic acids: General introduction, synthesis of peptides and amino acids, End group analysis, structural features of insulin, vasopressin and oxytocin, structural features of DNA & RNA
   - **d)** Antibiotics: Classification of antibiotics, structural details of penicillins and tetracyclines, polypeptide antibiotics
   - **e)** Flavonoids: Detailed chemical account of rutin and quercetin

f) Triterpenoids: A general chemical treatment and structural elucidation of terpenoids

g) Coumarins: General methods of isolation and purification and structural determination of xanthotoxin and psoralene

III. MEDICINAL CHEMISTRY

The following topics will be discussed keeping in view the recent advances:

1. Cardiovascular agents: Anti-hypertensive agents, antiarrhythmic agents, antihyperlipidemic agents, antianginal agents
2. Psychopharmacological agents: Antipsychotic agents – Introduction, biochemical basis of mental disorders, development of antipsychotic agents (Phenothiazines, Butyrophenones), atypical antipsychotic agents; Antidepressant drugs – Introduction, development of tricyclic antidepressants, monoamine oxidase inhibitors, selective serotonin-reuptake inhibitors, atypical antidepressants, lithium salts; Antianxiety Agents – Introduction, medicinal chemistry of benzodiazepines, SAR of benzodiazepine derivatives, medicinal chemistry of non-benzodiazepines, serotonin-reuptake inhibitors, development of meprobamate and analogues, atypical anxiolytic agents
3. Chemotherapy: Antiviral agents including the development in chemotherapy for AIDS, drugs for neoplastic diseases
4. Drugs affecting immune responses
5. Radioprotective drugs
6. Analgesics and anti-inflammatory agents: Prostaglandins, nonsteroidal drugs, steroidal drugs, endorphins
7. Diuretics

SPECIALIZATION: PHARMACOLOGY

I. BASIC PRINCIPLES OF DRUG THERAPY AND CLINICAL PHARMACOLOGY

1. Definition, scope, organization and growth of clinical pharmacology, cellular transduction mechanisms, clinical pharmacokinetics, monitoring of drug therapy, adverse drug reactions, patient compliance, pharmacogenetics, paediatric and geriatric pharmacology, drug interactions, drug therapy during pregnancy and lactation
2. Drugs acting on the autonomic nervous system
   - **a)** Neurotransmission: The autonomic and somatic motor nervous system
   - **b)** Muscarinic receptor agonists and antagonists
   - **c)** Anticholinesterase agents
   - **d)** Agents acting at the neuromuscular junction and autonomic ganglia
   - **e)** Catecholamines, sympathomimetic drugs and adrenergic receptor antagonists, ocular pharmacology
   - **f)** 5-Hydroxy tryptamine (Serotonin) receptor agonists and antagonists
3. Drugs acting on the Central Nervous System
   - **a)** Neurotransmission and the central nervous system
   - **b)** History and principles of anaesthesiology
   - **c)** General anaesthetics
   - **d)** Local anaesthetics
   - **e)** Hypnotics, sedatives and ethanol
   - **f)** Drugs and the treatment of psychiatric disorder – psychosis; Anxiety – depression and mania
   - **g)** Drugs effective in the therapy of epilepsy
   - **h)** Drugs effective in the therapy of migraine
   - **i)** Treatment of central nervous system degenerative disorders
   - **j)** Opioid analgesics and antagonists
   - **k)** Drug addiction and drug abuse
4. Autacoids: Drug therapy of inflammation
   - **a)** Introduction
   - **b)** Histamine, bradykinin and their antagonists
   - **c)** Lipid-derived autacoids: Eicosanoids and platelet activating factor
   - **d)** Analgesic-antipyretic drugs, anti-inflammatory agents and drugs employed in the treatment of gout
   - **e)** Drugs used in the treatment of asthma
5. Drugs effecting renal, blood and cardiovascular function
   - **a)** Diuretics
   - **b)** Drugs used in the treatment of myocardial ischemia
   - **c)** Antihypertensive agents and the drug therapy of hypertension
   - **d)** Pharmacological treatment of heart failure
   - **e)** Antiarrhythmic drugs
   - **f)** Drugs used in the treatment of hyperlipoproteinemias
   - **g)** Heamatopoietic agents: Growth factors, minerals and vitamins
   - **h)** Anti-coagulant, thrombolytic and antiplatelet drugs

II. RECENT ADVANCES AND EMERGINT TRENDS IN PHARMACOLOGICAL SCIENCES

1. Digestive system
   - **a)** Pharmacotherapy of peptic ulcer, diarrhoea, constipation
   - **b)** Agents affecting gastrointestinal water, flux and motility, emesis and antiemetics, bile acids and pancreatic enzymes
2. Therapy of Infectious diseases
   - **a)** General principles, antibacterial drugs – sulphonamides, quinolones, penicillins, cephalosporins, tetracyclines, chloramphenicol
   - **b)** Drugs used in the chemotherapy of protozoal infections – malaria
   - **c)** Drugs used in the chemotherapy of Protozoal infections – trypanosomiasis, leishmaniasis, amebiasis, giardiasis, trichomoniasis, and other protozoal infections
   - **d)** Drugs used in the chemotherapy of helminthiasis
   - **e)** Drugs used in the chemotherapy of leprosy, tuberculosis, fungal infections, viral infections
   - **f)** Drugs used in the chemotherapy of neoplastic diseases
   - **g)** Immunomodulators – immunosuppressive agents and Immunostimulants
   - **h)** Newer chemotherapeutic agents
3. Hormones and hormone antagonists
   - **a)** Adenohypophyseal hormones and their hypothalamic releasing factors
   - **b)** Hormones of posterior pituitary
   - **c)** Thyroid and antithyroid drugs
   - **d)** Estrogens and progestins, antifertility agents
   - **e)** Androgens
   - **f)** Adrenocorticotropic hormones – adrenocortical steroids and their synthetic analogs, inhibitors of the synthesis and actions of adrenocortical hormones
   - **g)** Insulin, oral hypoglycaemic agents and the Pharmacology of pancreatic hormones
   - **h)** Agents affecting calcification and bone turnover – calcium phosphate, parathyroid hormones, vitamin D, Calcitonin and other compounds
   - **i)** Vasopressin and other agents affecting the renal conservation of water
4. Emerging trends & recent advances in
   - **a)** Receptor and G-protein
   - **b)** Cyclic nucleotides
   - **c)** TNF, apoptosis
   - **d)** Ion channel modulators
   - **e)** Neurosteroids and cannabinoids
   - **f)** Nitric oxide
   - **g)** ANF, anti-oxidants: Melatonin
   - **h)** Gene therapy
   - **i)** Neuropeptide, Substance P, Angiotensin II modulators

III. PHARMACOLOGICAL METHODS AND TOXICOLOGY

1. Principles of pharmacological and clinical evaluation of drugs
2. Pharmacological Techniques to evaluate drugs belonging to following categories
   - **a)** Antipsychotics, antianxiety agents, nootropics, antidepressants, antiparkinsonian agents, antiepileptics, analgesics, anti-inflammatory agents, local anaesthetics
   - **b)** Antihypertensives, antiarrhythmics, anti-atherosclerotics, drugs for myocardial infarction
   - **c)** Antiulcer drugs, antidiabetics, antitussives
   - **d)** Evaluation of antioxidants
   - **e)** Transgenic animals, genetically prone animal models
   - **f)** Anti-cancer drugs
   - **g)** *In vitro* techniques
   - **h)** Antifertility agents
3. Drug toxicity, safety evaluation of new drugs
4. Regulations for laboratory animal care and ethical requirements

SPECIALIZATION: PHARMACOGNOSY & PHYTOCHEMISTRY

I. ADVANCES IN PHARMACOGNOSY

1. Introduction: General introduction to pharmacognosy and its importance in herbal drug industry, Classification with special reference to chemotaxonomy, Pharmacognostical evaluation and their importance in raw material standardization with suitable examples
2. Genetics in Pharmacognosy: Mendel's laws of hereditary and their application to pharmacognosy, chemical races, selections, hybridization, polyploidy, mutation, Plant growth hormones – application and effect on plant growth and its constituents
3. Comparative Phytochemistry: Relationship between phytochemistry and taxonomy, comparative phytochemistry of alkaloids, flavonoids and c – glycosides
4. Plant tissue culture techniques and its application in relation to phytopharmaceuticals: Introduction, techniques of initiation and maintenance of various types of cultures, Immobilized cell techniques, Biotransformation studies including recent developments in production of biologically active constituents in static, suspension and hairy root cultures, Bioreactors for production of biologically active constituents and other applications of plant tissue culture techniques
5. Recent advances in the field of pharmacognosy with special reference to anticancer, antidiabetic, anti-inflammatory, hepatoprotective, adaptogenic and immunomodulating drugs of plant origin, Skin irritants and sensitizing agents from plant and marine products of medicinal importance, Plant sweeteners

II. PHYTOCHEMISTRY & BIOGENESIS

1. General methods of phytochemical & biological screening, isolation and purification of plant constituents
2. Natural sources, extraction, purification, isolation and characterization of the following phytopharmaceuticals
   a) Alkaloids – Morphine, Quinine
   b) Glycosides – Sennosides, Glycyrrhizine, Asiaticosides, Diosgenin, Solasodine, Rutin
3. Industrially important volatile oils: Natural occurrence, chemistry, ontogenic variation and trade
4. Methods of investigation of biogenetic pathways
5. Biogenetic pathways for the production of phytopharmaceuticals, such as Alkylamine (Ephedra), Pyridine, Piperidine (Lobelia), Tropane (Belladonna), Quinoline (Cinchona), Isoquinoline (Opium), Diterpene (Aconite), Indole (Ergot), Cardiac glycosides, Coumarins and Flavones
6. Study of some herbal formulation as drug and cosmetics

III. CULTIVATION & STANDARDIZATION OF MEDICINAL PLANTS

1. Preparation of herbarium – specifications, use of flora and keys of plant identification, Microtomy and advanced histological techniques as applied to pharmacognostical specimen, Pharmacognostical drawings and macro and microphotography, Quantitative microscopy as applied to drug evaluation and pollen grain analysis
2. Agrotechnology of medicinal plants: Ecotypic, Phenotypic and Genotypic Variability affecting phytopharmaceuticals, Prospects and economics of medicinal and aromatic plants in India, Cultivation methods developed in India for the following plants of commercial significance – Glycyrrhiza, Ipecac, Mentha, Poppy, Psyllium and Senna, Tropane alkaloid and Steroid containing plants
3. Application of chromatographic techniques such as column, paper, TLC, HPTLC, GLC, HPLC and DCCC in the isolation and purification of phytopharmaceuticals
4. Applications of UV, IR, NMR, 1HNMR, 13CNMR and Mass spectroscopy for structural elucidation of phytopharmaceuticals, Standardization and quality procedures for the assay of plant products

SPECIALIZATION: PHARMACY PRACTICE

I. CLINICAL PHARMACY, PHARMACOKINETICS AND TOXICOLOGY

1. Definition, development and scope of clinical pharmacy
2. Clinical pharmacokinetics and pharmacodynamics
   - **a)** Volume of distribution, clearance, plasma protein binding, concentration dependent clearance, flow dependent clearance, multicompartment models, physiologic model, pharmacodynamic models, time course of drug action, cumulative effects of drugs, steep concentration effect curves
   - **b)** Hysteresis, proteresis, target concentration strategy, variability and control strategies in quantitative therapeutics bioavailability, drug biotransformation
3. Clinical evaluation of new drugs: Clinical trials, various phases of clinical trials, design and execution of trials in different clinical settings
4. Clinical laboratory tests and studies of imaging pharmaceuticals (contrast media)
5. Drugs in special patient groups: Pregnancy and nursing, neonates and children, elderly
6. Clinical importance of genetics in drugs effects
7. Drug therapy monitoring: Medication chart view, clinical review, TDM pharmacist interventions, ward round participation, adverse drug reaction management, medication history and patient counselling, drug utilization evaluation (DUE) and review (DUR), quality assurances of clinical pharmacy services, Patient data analysis, introduction to available information sources
8. Introduction to toxicology: Occupational and environmental toxicology, chelators and heavy metal intoxication, insecticide poisoning, toxic potentials of over the counter agents, dermatological toxicity, ototoxicity, nephrotoxicity, hemopoietic toxicity, carcinogenicity and teratogenicity, ocular toxicity, cardiotoxicity, hepatotoxicity, pulmonary toxicity, neurotoxicity, management of patient during drug toxicity (emergency treatment of poisoning), management and functioning of poisons information Centre (day and night)

II. APPLIED PHARMACOTHERAPEUTICS INCLUDING PATHOPHYSIOLOGY

1. Cardiovascular system – Hypertension, congestive cardiac failure, ischaemic heart disease, arrhythmias, hyperlipidaemias
2. Respiratory system – Asthma, chronic obstructive airways disease, drug induced pulmonary diseases
3. Renal system – Acute renal failure, chronic renal failure, renal dialysis and transplantation, drug dosing in renal impairment, drug induced renal disease, electrolytes and fluid balance
4. Haematological disease – Anaemia, thrombo-embolic disorder, drug induced haematological disorder
5. Endocrine system – Diabetes, thyroid diseases, oral contraceptives, hormone replacement therapy, osteoporosis
6. Nervous system – Epilepsy, Parkinson's disease, stroke and transient ischaemic attacks, headache, Alzheimer's disease, Huntington's chorea

7. Psychiatric disorders – Schizophrenia, depression, anxiety disorders, sleep disorder
8. Gastrointestinal system – Ulcer disease, inflammatory bowel diseases, hepatitis, jaundice, drug dosing in liver dysfunction, diarrhoea and constipation
9. Pathophysiology of inflammation and repair, immunology basic principles
10. Rheumatic diseases – Rheumatoid arthritis, gout, juvenile rheumatoid arthritis
11. Infectious diseases – Meningitis, respiratory tract infections, gastroenteritis, pneumonia, bacterial endocarditis, septicaemia, otitis media, urinary tract infections, tuberculosis, leprosy, protozoal infections, helminthiasis, HIV, opportunistic infections, fungal infections
12. Skin and sexually transmitted diseases – Psoriasis, acne, eczema, scabies, syphilis and gonorrhoea
13. General principles of cancer chemotherapy – Oncology cell cycle, commonly used cytotoxic drugs, chemotherapy of lung cancer, breast cancer, head and neck cancer, prostate cancer, cervical cancer, haematological malignancies
14. Ophthalmology – Glaucoma and eye infections
15. Pain management – Pain pathways, analgesics and NSAIDs, opiates, local anaesthetics, neuralgia including trigeminal and glossopharyngeal neuralgias
16. Nutrition – Malnutrition and deficiency states, enteral and parenteral nutrition

III. HOSPITAL AND COMMUNITY PHARMACY

1. Community pharmacy
   - **a)** Introduction to the concept of community pharmacy, its activities and professional responsibilities
   - **b)** The role of the community pharmacy and its relationship to other local health care providers
   - **c)** Prescribed medication order interpretation and legal requirements
   - **d)** Patient counselling in community pharmacy
   - **e)** Over the counter (OTC) sales
   - **f)** Services to nursing homes/clinics
   - **g)** Community pharmacy management: Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy
   - **h)** Code of ethics for community pharmacists
   - **i)** Polypharmacy and its implication
2. Hospital pharmacy
   - **a)** The role of hospital pharmacy department and its relationship to other hospital departments and staff
   - **b)** Hospital Drug policy: Drug formulary committee and guidelines, other hospital committees such as infection control committee and research & ethics committee
   - **c)** Hospital Pharmacy Management: Staff (professional and non-professional), materials (drugs, non-drugs, consumables), financial (drug budget, cost centres, sources of revenue collection), policy, maintenance and planning, infrastructure requirements (building furniture and fittings, specialized equipment, maintenance and repair), workload statistics, hospital formulary

d) Organization of hospital pharmacy services
e) Drug distribution: Purchasing, warehousing (storage conditions, expiry date control, recycling of drugs, stocktaking drug recalled, drug distribution method, ward stock, individual patient dispensing, specific requirements for inpatients, outpatients, casualty emergency, theatre, ICU/ICCU, drugs of dependence
f) Manufacturing: Sterile and non-sterile production, including total parental nutrition, cytotoxics
g) Radio Pharmaceuticals: IV additive service, pre-packing and labelling, quality control
h) Research: Practice based research, research support including clinical trials, laboratory-based research
i) Pharmacoepidemiology: Definitions and scope, methods (qualitative, quantitative and meta-analysis models), system for monitoring drug effects, advantages and disadvantages of pharmacoepidemiology
j) Pharmacoeconomics: Definitions and scope, types of economic evaluation, cost models and cost effectiveness analysis
k) Public health policy and health care system
l) Rational prescription and prescription writing
m) Communication skills: Principle and elements of communications skills, non-verbal communication in pharmacy, barriers in communication, listening skills, explaining skills and ethics in communication
n) Adverse drug reactions: incidence of adverse drug reactions, recognizing adverse drug reactions, types of adverse drug effects, hypersensitivity reactions , selected adverse effects on selected organs, drug addiction and drug abuse, drug interactions – definition of drug interactions, principles of prevention of adverse drug interactions, clinical importance of drug interactions involving enzyme induction, pharmacoepidemiology documentation of clinical pharmacokinetic and clinical pharmacology data for commonly used drug, management of drug information's services