VISHWAKARMA UNIVERSITY
Maximising Human Potential

Syllabus for Ph.D. (Pharmaceutical Sciences) Entrance Exam Paper -II

UNIT-1

Chemistry: Modern Pharmaceutical Analytical Techniques: Principles, working and applications of all spectroscopic techniques and chromatographic techniques.

Organic Chemistry: Structure and bonding, Stereochemistry: R and S configuration, optical activity, and conformational analysis.
Basic Aspects of Organic Chemistry: Organic intermediates, Synthon approach and retrosynthesis applications, Green Chemistry, Photochemical Reactions, Stereochemistry & Asymmetric Synthesis, Process chemistry: Unit Processes: Nitration, Halogenation, Oxidation, Reduction, Fermentation, Reaction progress kinetic analysis
Medicinal Chemistry: Structure-Activity Relationships (SAR) of common therapeutic agents (antibiotics, analgesics, anti-inflammatory drugs, etc.). Principles of prodrug design and drug metabolism. Drug discovery, Computer Aided Drug Design, QSAR, Prediction and analysis of ADMET properties.
Inorganic Chemistry: limit tests (e.g., for heavy metals), Role of isotopes in diagnostics and therapy (e.g., radiopharmaceuticals), Carbohydrate and Lipid metabolism (glycolysis, gluconeogenesis, TCA cycle).

UNIT-2

Pharmacology:

Basic Principles: Pharmacodynamics: Drug-receptor interactions, dose-response relationships, and signaling pathways. Pharmacokinetics: Absorption, distribution, metabolism (phases I & II), and excretion (ADME).Factors affecting drug action: Age, genetics, disease states, and drug interactions.

Systemic Pharmacology: Drugs acting on the autonomic and central nervous systems. Pharmacology of cardiovascular, respiratory, renal, endocrine, and gastrointestinal systems. Chemotherapy: Antibiotics, antivirals, antifungals, and anticancer drugs.

Adverse Drug Reactions and Drug Interactions: Types, mechanisms, and pharmacovigilance.

Pharmacogenetics and Toxicology: Genetic influences on drug response. Toxicological principles: Teratogenicity, carcinogenicity, and organ toxicities.

Systemic Pharmacology and Therapeutics: belonging to Central Nervous System (CNS) and Autonomic Nervous System (ANS), Cardiovascular Pharmacology, Endocrine Pharmacology: Renal, gastrointestinal tract, respiratory system, and uterine motility, Antibiotics, Antimalarials, antitubercular, and antileprotic agents, antifungal and antiviral drugs and Chemotherapy of malignancies.

UNIT-3

Pharmaceutics:

Pre-formulation Studies, Kinetic principles and stability testing, Introduction to pharmacokinetics, ADME, Bioavailability and bioequivalence studies, GMP, validation, and scale-up techniques, solid oral dosage forms, Novel drug delivery systems like nanoparticles, lipid based drug delivery systems, monoclonal antibodies, Fundamental, design and fabrication of controlled release drug delivery system. Recombinant DNA technology and its applications, Sterilization techniques,

UNIT-4	

Pharmacognosy and Natural Products:

Sources, identification, and evaluation of plant-based medicines. Global and traditional practices: Ayurveda, Unani, Siddha, Yoga, Homeopathy and Chinese medicine . WHO guidelines on herbal medicine standardization.

Secondary Metaboliltes:Biosynthetic pathways in production of secondary metabolites. Biosources, chemistry, chemical test, uses and analysis of alkaloids, glycosides, terpenoids, tannins, flavonoids, and resins. Methods of extraction, isolation, and analysis using spectroscopy and chromatography.

Herbal Drug Applications: Drugs from natural origin with anti-inflammatory, antimicrobial, hepatoprotective and anticancer activity. Herbal cosmetics: Sources of raw materials, formulations and application in skincare, haircare and oral hygiene. Herbal formulations including phytosomes. Sources and uses of raw materials: Fixed oils, waxes, antioxidants; Nutraceuticals.

UNIT-5	

Pharmaceutical Quality Assurance:

Quality Management System: Dimensions of Quality, Quality as a Strategic Decision, Customer Focus, TQM, ISO, ICH Q8, Q9 & 10 guidelines, OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements. Six System Inspection model, Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Statistical Process control, Benchmarking. GLP, GMP, CPCSEA guidelines. cGMP guidelines according to schedule M, USFDA, and CDER. Pharmaceutical Inspection Convention, Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Documentation in pharmaceutical industry.

Pharmaceutical Manufacturing Technology, Product Development and Technology Transfer : Manufacturing operations and controls, Principles of Drug discovery and development, Pre-formulation studies, Pilot plant scale up, Pharmaceutical packaging, Technology transfer, Hazard and risk management, Production planning, Aseptic process technology, Non sterile manufacturing process technology, Quality by design (QbD) and process analytical technology (PAT).

Pharmaceutical Validation: Calibration, Qualification and Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan, Qualification of manufacturing equipment, Qualification of laboratory equipment's, Process Validation, Cleaning Validation, General Principles of Intellectual Property (IPR).

Audits and Regulatory Compliance: Audit process, Management of audit, Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality

assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Auditing of vendors and production department Auditing of Microbiological laboratory.

References:

1. Pharmaceutical Organic chemistry by any author.
2. Organic chemistry by Morrison and Boyd
3. The theory and practice of Industrial pharmacy by Leon Lachman and Liebermann
4. Text book of Medicinal chemistry by Ashutosh kar
5. Pharmacology by any authors
6. Pharmacognosy by C.K.Kokate
7. Pharmaceutical quality assurance by authors.