SWAMI RAMANAND TEERTH MARATHWADA UNIVERSITY, NANDED

FACULTY OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

PRE Ph.D. ENTRANCE EXAMINATION

Section-B: Multiple Choice Questions

Typically, an aspirant should know the physical and chemical properties of excipients for efficacy and efficiency of drug delivery systems, design of DDS overcoming physical properties of pharmaceuticals for achieving compatibility release and stability, technical operations employed by

pharmaceutical manufacturers to produce DDS on large scale achieving reproducibility, efficacy with every unit of dosage form manufactured, the common manufacturing stresses observed while manufacturing of different dosage forms at large scale, the basic concept of development of Novel drug delivery systems, specialized aspects of Novel drug delivery technique capable of controlling the rate of drug delivery, sustaining the duration of therapeutic activity, targeting the delivery of drug to a tissue in an effective, reliable, reproducible and safe manner and concepts of cosmetic technology.

General structural features of agents belongs to therapeutic class; their relevant physico-chemical properties, chemical reactions, structural & chemical influence on mechanism of action, metabolism & synthesis along with process of drug invention, discovery, design, identification, interpretation of mode of interaction at the molecular level, SAR, QSAR; Principles involved in instrumental methods of chemical analysis, interpreting the data of spectroscopic analysis and chromatography & their applications.

Sources, properties, physiological actions, ADME and therapeutic uses of drugs useful in infectious and non-infectious diseases; disease relevant targets for drug action, consequence of drug-receptor interaction at the molecular level, drug specificity, and selective toxicity; factors influencing pharmacokinetic and pharmacodynamic profile of drugs, concept of bioavailability and bioequivalence along with concepts of rational of drug therapy, toxicology, essential drugs and application of ADME principles in clinical situations; drug discovery process and regulatory aspects; International guidelines (for eg. ICH), preclinical pharmacological screening methods, concepts of Bioassay, alternative methods of screening procedures like cell-line technique and Biostatistics.

Pathophysiology of common diseases; Basic Principles of Cell Injury and Adaptations: Causes of Cellular injury, pathogenesis, morphology of cell injury, adaptations and cell death; Basic Mechanisms involved in the process of inflammation and repair: Vascular and cellular events of acute inflammation, chemical mediators of inflammation, pathogenesis of chronic inflammation, brief outline of the process of repair;. Pathophysiology of Common Diseases: AIDS, Asthma, diabetes, rheumatoid arthritis, gout, ulcerative colitis, neoplasia, psychosis, depression, mania, epilepsy, acute and chronic renal failure, hypertension, angina, congestive heart failure, atherosclerosis, myocardial infarction, congestive heart failure, peptic ulcer, anemias, hepatic disorders, tuberculosis, urinary tract infections and sexually transmitted diseases.

Classical botany associated with scientific and systematic study including chemistry, tests, cultivation, collection, adulterants and storage of crude drugs belonging to group of alkaloids, glycosides, tannins, terpinoids, steroids, bioflavonoid, Purines and lipids along with their general

methods of isolation, purifications, identification, estimation and biogenesis of Phytoconstituents; WHO Guidelines of assessment of crude drugs and herbal formulations, concepts of Ayurvedic preparations, plant tissue culture with biotechnological principles and techniques for obtaining & improving quality of natural products; Phytochemical Screening: Preparation of extracts, Screening of alkaloids, saponins, cardenolides and bufadienolides, flavonoids and leucoanthocyanidins, tannins and polyphenols, anthraquinones, cynogenetic glycosides, amino acids in plant extracts. Marine Pharmacognosy: Novel medicinal agents from marine sources; Natural allergens and photosensitizing agents and fungal toxins; Herbs as health foods; Herbal cosmetics. Standardization and quality control of herbal drugs.

Studies of Traditional Drugs: Common vernacular names, botanical sources, morphology, chemical nature of chief constituents, pharmacology, categories and common uses and marketed formulations of following indigenous drugs: Amla, Kantkari, Satavari, Tylophora, Bhilawa, Kalijiri, Bach, Rasna, Punamava, Chitrack, Apamarg, Gokhru, Shankhapushpi, Brahmi, Adusa, Atjuna, Ashoka, Methi, Lahsun, Palash, Guggal, Gymnema, Shilajit, Nagarmotha and Neem; The holistic concept of drug administration in traditional systems of medicine; Introduction to ayurvedic preparations like Arishtas, Asvas, Gutikas, Tailas, Chumas, Lehyas and Bhasmas.

Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion, ion-pair formation and pinocytosis); Factors influencing absorption- biological, physico-chemical, physiological and pharmaceutical; Drug distribution in the body, plasma protein binding. Significance of plasma drug concentration measurement, Compartment model- Definition and Scope; Pharmacokinetics of drug absorption - Zero order and first order absorption rate constant using Wagner-Nelson and residual methods; Volume of distribution and distribution coefficient; Compartment kinetics- One compartment and two compartment models, Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intravascular and oral route; Clearance concept, mechanism of renal clearance, clearance ratio, determination of renal clearance, Extraction ratio, hepatic clearance, biliary excretion, extra-hepatic circulation; Non-linear pharmacokinetics with special reference to one compartment model after I.V. drug administration; Measures of bioavailability, Cmax, tmax, Keli and Area Under the Curve (AUC); Design of single dose bioequivalence study and relevant statistics; Review of regulatory requirements for conducting bioequivalent studies.

Control of microbes by physical and chemical methods; Disinfection, factors influencing disinfectants, dynamics of disinfection, disinfectants and antiseptics and their evaluation Sterilization: different methods, validation of sterilization methods & equipments; Sterility testing of all pharmaceutical products. Microbial assays of antibiotics, vitamins & amino acids; Immunology and Immunological Preparations: Principles, antigens and heptans, immune system, cellular/humoral

immunity, immunological tolerance, antigen-antibody reactions and their applications; Hypersensitivity, active and passive immunization. Vaccines and sera: their preparation, standardization and storage.

Pharmaceutical Legislations: A brief review; Drugs & Pharmaceutical Industry - A brief review; Pharmaceutical Education - A brief review; An elaborate study of the followings: Pharmaceutical Ethics; Pharmacy Act 1948; Drugs and Cosmetics Act 1940 and Rules 1945; Medicinal & Toilet Preparations (Excise Duties) Act 1955; Narcotic Drugs & Psychotropic Substances Act 1985 & Rules; Drugs Price Control Order; A brief study of the following Acts with special reference to the main provisions and the latest amendments: Poisons Act 1919; Drugs and Magic Remedies (Objectionable Advertisements) Act 1954; Medical Termination of Pregnancy Act 1970 & Rules 1975; Prevention of Cruelty to Animals Act 1960; States Shops & Establishments Act & Rules; Insecticides Act 1968; AICTE Act 1987; Factories Act 1948; Minimum Wages Act 1948; Patents Act 1970; A brief study of the various Prescription/Non-prescription Products; Medical/Surgical accessories, diagnostic aids, appliances available in the market.

Principals involved and procedures adopted in dispensing of : Typical prescriptions like mixtures, solutions, emulsions, creams, ointments, powders, capsules, pastes, jellies, suppositories, ophthalmic, pastilles, lozenges, pills, lotions, liniments, inhalations, paints sprays tablet triturates, etc; Incompatibilities: Physical and chemical incompatibilities, inorganic incompatibilities including incompatibilities of metals and their salts, non-metals, acids, alkalis, organic incompatibilities. Purine bases, alkaloids, pyrazolone derivatives, amino acids, quaternary ammonium compounds, carbohydrates, glycosides, anaesthetics, dyes, surface active agents, correction of incompatibilities. Therapeutic incompatibilities; Organization and Structure of hospital pharmacy: Organization of a hospital and hospital pharmacy, Responsibilities of a hospital pharmacist, Pharmacy and therapeutic committee, Budget preparation and Implementation. Central Sterile Supply Unit and their Management: Types of materials for sterilization, packing of materials prior to sterilization, sterilization equipments, Supply of sterile materials. Drug Information Services: Sources' of Information on drugs, disease, treatment schedules, procurement of information, Computerized services (e.g., MEDLINE), Retrieval of information, Medication error- types of medication errors, correction and reporting.

Filtration and Centrifugation: Theory of filtration, continuous and batch filters, filter aids, filter media, industrial filters including filter press, rotary filter, edge filter, etc. Factors affecting filtration, filtration, optimum cleaning cycle in batch filters. Principles of centrifugation, industrial centrifugal filters, and centrifugal sedimenters; Dehumidification and Humidity Control: Basic concepts and definition, wet bulb and adiabatic saturation temperatures, Hygrometric chart and measurement of humidity, application of humidity measurement in pharmacy, equipments for dehumidificat4ion operations.

Biochemistry in pharmaceutical sciences: The concept of free energy, Determination of change in free energy - from equilibrium constant and reduction potential, bioenergetics, production of ATP and its biological significance; Enzymes: Nomenclature, enzyme kinetics and their mechanism of action, mechanism of inhibition, enzymes and iso-enzymes in clinical diagnosis; Co-enzymes: Vitamins as co-enzymes and their significance; metals as cofactors and their significance; metabolic pathways and their clinical importance of Carbohydrate, Lipid & Protein metabolism.

Quality Assurance: GLP, ISO 9000, TQM, Quality Review and Quality documentation, Regulatory control, regulatory drug analysis, interpretation of analytical data, Validation, quality audit: quality of equipment, validation of equipment, validation of analytical procedures.

Principles of Toxicology: Definition of poison, general principles of treatment of poisoning with particular reference to barbiturates, opioids, organophosphorous and atropine poisoning, Heavy metals and heavy metal antagonists.

I) Pharmaceutics: _____

Unit-1 Research Methodology:

Typically, an aspirant should know Meaning & Objectives of research, types of research, approaches to research; Research methods, research process; Criteria for good research, qualitative & quantitative research methods; Selection of research problem, research design; meaning, concept & features of research design, experimental design, plan of research work; Primary & secondary data collection method, identification of sources of information, searching and classifying information; compilation, processing & analyzing of data & information; Principles of validity & reliability of research work, ethical aspects of research methodology; Developing research proposals, Format of research proposals, Individual & Institutional research proposals; Interpretation of Results and Presentation.

Unit-2 Regulatory Affairs & IPR:

Concepts of total quality management, Good laboratory practices and ISO; Quality assurance & quality control for APIs and other intermediates in process & finished products; Good clinical practice guidelines. US regulatory practices, ICH guidelines; Regulatory Acts: Drugs & Cosmetic act-1940 & rules 1945 with special relevance to schedule M, Y, U; latest drug price control order & latest drug policy.

Intellectual Property Rights: Introduction, Scope, Objectives of IPR in pharmacy, Indian legal system & its role in IPR; Concept of property with respect to intellectual creativity; Tangible & Intangible property, concept of IPR, scope & nature of patents, copyrights, trade mark, geographical limitations; Indian Patent Act 1970, Patenting in India & abroad, practical aspects of patent filing, components of a patent application in India.

Unit-3 Analytical Techniques:

Introduction, basic principles, applications & instrumentation of spectroscopic methods viz, UV-Visible, IR, NMR & Mass spectroscopy. Classification of chromatographic methods based on mechanism of separation & basic principles of GC, HPLC, HPTLC.

Unit-4 Preformulation:

Techniques for physico-chemical characterization of Drug and Excipient significance and methods for evaluation of drug-excipient, excipient-excipient and drug containers/closures interactions and incompatibilities. Physiochemical aspect: pKa, Partition coefficient, Hygroscopicity, Polymorphism & crystal habbits, solubility etc.

Biological aspects: Role of physicochemical parameters on drug absorption and their implications, routes of administrations and implication on bioavailability.

Unit-5 Surfactant & polyphasic system:

Phase behavior of surfactant in binary and ternary Systems; Factors affecting phase behavior; Micellization, micelle structure, shape, size factor affecting CMC and micellar size, thermodynamics and kinetics of micelle formation; Pharmaceutical aspects of solubilization in non-aqueous systems, interaction with polymers and oppositely charged species; SEDDS & SMEDDS, Multiple emulsions, Ternary & Pseudoternary phase diagrams, Zeta potential.

Unit-6 Pharmaceutical Production Technology:

a) **Size reduction:** Objectives and mechanisms of size reduction, factors affecting size reduction, laws governing energy and power requirements of a mill, colloid mill, high pressure homogenization, microfluidizers, and ultrasonicators.
b) **Mixing**: Theory of mixing and types of mixers including high speed mixers, ultrasonic mixers, industrial mixer-Nauta mixer and RMG, Diosna.
c) **Filtration and centrifugation**: Theory of filtration, filter media, factors affecting filtration, industrial filters, optimum-cleaning cycle in batch filters, Principles of centrifugation, industrial centrifugal filters and centrifugal sedimeters, ultracentrifugation.
d) **Drying**: Mechanisms of heat transfer, internal mechanism of moisture flow, psychrometry, drying mechanism, Moisture content and mechanism of drying, rate of drying and time of drying, Dryers used in pharmaceutical industries and special drying methods, e.g., tray, fluidized bed, spray, freeze, tunnel, microwave, granulators-cum-driers, IR dryers.

Unit-7: Pharmaceutical Technology:

Tableting Technology, Pelletization technology, Capsulation technology, parenteral technology; **Stability Testing:** Physicochemical and biological factors affecting stability of drugs, Method to find out degradation pathways, Determination of shelf life by accelerated stability testing.

Unit-8 Drug Delivery Systems:

Controlled release drug delivery system, Transdermal drug delivery systems, Mucoadhesive Drug Delivery Systems, Occular Drug Delivery Systems, Targeted Drug Delivery Systems, Intrauterine Drug Delivery Systems and Polymers Science.

Unit-9 Bio-pharmaceutics and Pharmacokinetics:

Absorption, distribution, metabolism, excretion and protein binding; **Bioavailability and Bioequivalence studies:** Definition, Objective of bioavailability, Parameters of bioavailability, Determination of AUC; Estimating absorption rate of drugs; Measurement of bioavailability-Pharmacokinetic methods and Pharmacodynamic methods; Drug dissolution rate & bioavailability; *In-vitro in-vivo* correlation.

Unit-10 Dissolution Testing: Theories of drug dissolution,dissolution test apparatus, selection of dissolution medium, dissolution of different dosage form solids, suspensions, topical, suppositories and controlled release systems. Enhancement of dissolution rate. Biopharmaceutical classification system, In-vivo dissolution techniques, in vitro models for evaluation .

II) Pharmaceutical Chemistry:

Unit-1 Research Methodology:

Typically, an aspirant should know Meaning & Objectives of research, types of research, approaches to research; Research methods, research process; Criteria for good research, qualitative & quantitative research methods; Selection of research problem, research design; meaning, concept & features of research design, experimental design, plan of research work; Primary & secondary data collection method, identification of sources of information, searching and classifying information; compilation, processing & analyzing of data & information; Principles of validity & reliability of research work, ethical aspects of research methodology; Developing research proposals, Format of research proposals, Individual & Institutional research proposals; Interpretation of Results and Presentation.

Unit-2 Regulatory Affairs & IPR:

Concepts of total quality management, Good laboratory practices and ISO; Quality assurance & quality control for APIs and other intermediates in process & finished products; Good clinical practice guidelines. US regulatory practices, ICH guidelines; Regulatory Acts: Drugs & Cosmetic act-1940 & rules 1945 with special relevance to schedule M, Y, U; latest drug price control order & latest drug policy.

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Unit-3 Analytical Techniques:

Introduction, Basic principles, applications, instrumentation of spectroscopic methods viz., UV-Visible, IR, NMR & Mass spectroscopy. Classification of chromatographic methods based on mechanism of separation & basic principles of GC, HPLC, HPTLC.

Unit-04 STEREOCHEMISTRY:

Molecular dissymmetry, compounds with one, two or more unequal asymmetric carbon atoms and recimic modifications, configuration absolute and relative, synthesis of optically active compounds, conformations in cyclic compounds, optical isomerism, shapes of cyclohexanes and six-membered heterocyclic rings, shapes of rings other than six membered. Stereoselective synthesis, role of inductive, resonance and steric effects in structure and relativity. **CHIRAL TECHNOLOGY:** Introduction to chirality and Techniques used in asymmetric synthesis of Vitamin C, Ampicillin, dextra-propoxyphen, Citrenalol, Propranolol

Unit-05 MECHANISM STEREOCHEMISTRY AND APPLICATIONS OF:

Birch reduction, Clemensen reduction, Meerwein-Pondroff reduction, Oppennauer oxidation, Wolf Kishner reduction, Witting Reaction, Pinacol and related rearrangements, Beckmann rearrangement, Hoffman rearrangement, Claisen rearrangement, Schmidt, Lossen and Curtius rearrangement.

Unit-06 MEDICINAL CHEMISTRY OF:

a. Antiviral Agents and agents under development of HIV infection.

b. Immunosuppressant and Immunostimulants.

c. Agents used in Neurodegenerative disease Like Alzheimer's and Parkinsonism.

d. GABAnergic Agonists.

e. Anti TB agents

f. Antibiotics

g. Synthon approach

Definition of terms- disconnection, Synthon, functional group interconversions; Basic rules in disconnection; Use of Synthon approach in synthesis of following components: Trimethoprim, Ibuprofen, Propranolol, Piroxicam.

Unit-07 APPROACHES TO THE RATIONAL DESIGN OF ENZYME INHIBITORS:

a. Introduction

i) Enzyme inhibitors in Medicine

ii) Enzyme inhibitors in basic Research

iii) Drug Design based on Antagonism and Enzyme Inhibition

b. Rational design of non covalently & covalently binding enzyme inhibitors Rapid reversible inhibitors, slow & tight binding inhibitors, Transition state analogs, multi substrate inhibitors.

Unit-08 ROLE OF RECOMBINANT DNA TECHNOLOGY AND DRUG DISCOVERY:

Cloning DNA, expression of clonal DNA, manipulation of DNA sequence, information new biological targets for drug developments, novel biotechnology derived pharmaceutical products. Antibody, antisense oligonucleotide therapy and gene therapy.

Unit-09 Quantitative Structure Activity Relationship and Drug design:

a. History and development of QSAR

b. Drug-Receptor Interactions

c. Quantitative model parameters: lipophilicity, electronic and steric factors

d. Hansch Analysis, Free Wilson analysis, relationship between them and their application

e. Statistical methods-regression analysis, partial-least square analysis (PLS) and other multivariate statistical methods

f. 2D and 3D QSAR approaches

Unit-10 Chemistry of Natural Products:

a. Natural products as leads for new pharmaceuticals

b. Alkaloids

c. Steroids

d. Flavonoids

III) Pharmacology:

Unit-1 Research Methodology:

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Unit-3 Analytical Techniques:

Introduction, Basic principles, applications, instrumentation of spectroscopic methods viz., UV-Visible, IR, NMR & Mass spectroscopy. Classification of chromatographic methods based on mechanism of separation & basic principles of GC, HPLC, HPTLC.

Unit-4 Clinical Pharmacokinetics:

Introduction and basic concepts of ADME profile of drugs, absorption rate constant, volume of distribution, elimination rate constant, clearance, extraction ratio, area under curve (AUC), protein and tissue binding; Calculation of parameters from plasma and urine data; Bioavailability and Bioequivalence basic Principles, objectives, protocols and variation of bioavailability & bioequivalence, measurement, designing of bioavailability studies & interpretation of results; Physiological, Physico-chemical & formulation factors affecting bioavailability, enhancing bioavailability of drug products.

Unit-5 Drug Discovery Process:

Principles, techniques and strategies used in new drug discovery, basic concepts of combinatorial chemistry, high through screening, cell lines, and their applications.

Unit-6 Bioassay:

Bioassays: Basic principles of bioassays, official bioassays, experimental models, design of bioassays and statistical methods used in biological standardization.

Unit-7 Preclinical Drug Screening:

Standard techniques used in laboratory animals, euthanasia of experimental animals, Regulations for laboratory animal care and ethical requirements. Preclinical models employed and organization of screening of new drugs. Preclinical evaluation of drugs like Sedatives, hypnotics, Anxiolytic, antidepressants, antipsychotic, analgesics, antipyretics, anticonvulsants, Anti-inflammatory agents, Cardiac glycosides, antiarrythmics, antihypertensive, antianginals, antiatherosclerotic, Bronchodilators, Diuretics, Antitussive, Laxatives & antidiarrhoeals; Antiulcer, Hepatoprotective, Antidiabetic, Anticholinergics, Sympatholytics, Muscle relaxants, Antimalarials, Antiviral, Anticancer agents, Anthelmintic.

Unit-8 Molecular Pharmacology:

Introduction to Molecular Pharmacology; Techniques to study molecular pharmacology such as Western Blotting, Immunostaining, RT-PCR, Cloning, Cell Culture etc.; Recombinant DNA technology and its applications. Molecular Mechanism of drug action; Receptor occupancy and cellular signaling system such as G-Protein, cyclic nucleotides, calcium & phosphatidyl inositol, Ionic channels and their modulators; process of apoptosis, arachidonic acid metabolites, COX-2 regulators and their role in inflammation.

Unit-9 Clinical Pharmacology:

Introduction to clinical pharmacology, therapeutic monitoring of drugs; organization & types of clinical research; design and organization of phase-I to IV of clinical studies, ethics of clinical trials; Drug-drug, drug-food, drug-pollutants interactions; Principles of pediatric, geriatric pharmacology; drug therapy in pregnancy and lactation; Clinical aspects of drug therapy under neuropharmacotherapy, endocrinology, immunopharmacology, infectious pharmacology; concept of gene therapy.

Unit-10 Toxicology:

General principles of toxicology, toxicological evidence, common household poisons, qualitative & quantitative aspects of toxic effects, detoxification & disposition, Single dose and repeat dose toxicity studies; factors influencing such studies like species, sex, size, route and dose level; regulatory requirements, determination of effective dose & LD_{50} as per international guidelines, organ and system toxicology, reproductive toxicology assessment, mutagenicity and carcinogenicity.

IV) Pharmacognosy:

Unit-1 Research Methodology:

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research proposals, Format of research proposals, Individual & Institutional research proposals; Interpretation of Results and Presentation.

Unit-2 Regulatory Affairs & IPR:

Concepts of total quality management, Good laboratory practices and ISO; Quality assurance & quality control for APIs and other intermediates in process & finished products; Good clinical practice guidelines. US regulatory practices, ICH guidelines; Regulatory Acts: Drugs & Cosmetic act-1940 & rules 1945 with special relevance to schedule M, Y, U; latest drug price control order & latest drug policy.

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Unit-3 Analytical Techniques:

Introduction, Basic principles, applications, instrumentation of spectroscopic methods viz., UV-Visible, IR, NMR & Mass spectroscopy. Classification of chromatographic methods based on mechanism of separation & basic principles of GC, HPLC, HPTLC.

Unit-4 Cultivation of medicinal plants:

Definition, Eco-friendly farming, Organic farming, Biological farming, Nature farming, Alternate agriculture, Ecological agriculture, Objective of ecological farming, Good agricultural and harvesting practice

Unit-5 Cloning of plant cells and Gene mapping and molecular maps of plant genomes:

Different methods of cloning and its application. Advantages and disadvantages of plant cell cloning Transgenic plants, Application of transgenic plants with special reference to--

- Resistant to Herbicide, insects, fungus and viruses.
- Resistant to physiological stress.
- Production of Pytopharmaceuticals
- Edible vaccines

Plant Chromosome Analysis, Uses of PCR in gene mapping, Molecular Maps-RFLP,RAPD Physical maps using in-situ hybridization

Unit-6 Concept of standardization of plant drugs

Organoleptic evaluation of drugs including Gross morphology, sampling, preliminary examination and foreign matter, Microscopic evaluation of plant drugs**,** Physical evaluation of plant drug: Determination of moisture content, foreign organic matter, ash values, extractive values and swelling index. Refractive index, optical rotation and their applications in standardization of plant drugs; phytochemical evaluation of plant drug: General methods of assays for alkaloids, steroids, terpenoids, flavonoids, glycosides, tannins and coumarins. Fingerprint profiling of crude drugs and single and multicomponent herbal preparation. Stability testing of natural products

Unit-7 Standardization of herbal extracts as per WHO/CGMP Guidelines:

Physical, chemical, and toxicological standardization, qualitative and quantitative estimations exemplified by the methods of preparation of at least two standardized extracts. Stability studies for extracts.

Unit-8 Extraction, isolation, Purification, characterization and Screening Methods:

General method of phytochemical screening, isolation and purification of plant constituents, characterization of phytoconstituents by UV, IR, HPLC, HPTLC and GC-MS. Brief concept on biological screening of natural products with special reference to anti-inflammatory, hepatoprotective, antidiabetic, antioxidant and anticancer.

Unit-9 Herbal Product Development:

Preparation of liquid orals, tablets, capsules ,ointments ,creams and cosmetics Methods involved in monoherbal and polyherbal formulation with their merits and demerits; Excipients used in herbal formulation Compatibility studies Stability studies Bioavailability &Pharmacokinetic aspects for herbal drugs with examples of well known documented, clinically used herbal drugs; Quality Control of finished herbal medicinal products.

Unit-10 Natural product as lead compounds:

Approaches to discovery and developments of natural products as potential new drugs; selection and optimization of lead compounds for further development with suitable examples from CNS, Anticancer and cardiovascular drugs.

V) Quality Assurance:

Unit-1 Research Methodology:

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Unit-2 Regulatory Affairs & IPR:

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Unit-3 Analytical Techniques:

Introduction, Basic principles, applications, instrumentation of spectroscopic methods viz., UV-Visible, IR, NMR & Mass spectroscopy. Classification of chromatographic methods based on mechanism of separation & basic principles of GC, HPLC, HPTLC.

Unit-4 Good manufacturing practices:

GMP in manufacturing processing and quality control of drugs, control of facility, personal, production and process controls, packaging and labeling controls, documents, WHO GMP guidelines. GMP for ayurvedic products, Good clinical practice (GCP), Good laboratory practice (GLP), Good Pharmacy practice (GPP).

Unit-5 Validation:

Pharmaceutical process validation, equipment validation and sterile products validation, Validation of sterilization methods and equipment, Dry heat sterilization, Autoclaving, membrane filtration. Validation and audits of analytical procedures.

Unit-6 Quality control of pharmaceutical dosage forms:

Solid and semi-solid dosage forms, disperse systems and parenteral dosage forms, Validation and personnel.

Unit-7

Qualification, Validation and calibration of equipment, Validation of process like mixing, granulation, drying, compression filtration filling etc. Validation of air handling equipment in sterile and non-sterile areas, supply system, dematerialized, distilled water for injection and Validation of water.

Unit-8 Application of process analytical technology (PAT) in quality assurance

a.) Calibration and validation of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR spectrophotometer, Spectrofluorometer, HPLC, HPTLC and GC.

b.) Regulatory requirement in pharmaceutical analysis – US-FDA, ICH, PAC-ALTS: Post approval changes – analytical testing laboratory site etc. and Schedule M and Schedule Y.

c.) Analysis of drug from biological fluids.

d.) Application of analytical methods to product obtained through genetic engineering, Amino acid sequence analysis, tryptic mapping, ion exchange amino acid analysis, isoelectric focusing etc.

e.) Application of analytical methods to product obtained from natural sources (extracts, herbal formulations, isolated compounds, modern herbal formulations) (Compendial methods for evaluation of crude drug and herbal formulation)

f.) Dosage form impurity profile and its validation

g.) Organization & personnel, responsibilities, training and records. Equipment selection purchase specifications, maintenance, clean in place for analytical department.

Unit-9 Stability aspects: Basic concept and objectives of stability study.

• Regulatory requirement for stability studies: A very brief introduction to FDA and WHO guidelines. Detail study of ICH guidelines [Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C].

• Kinetic principles applied for stability evaluation and their applications in predicting shelf life and half life of pharmaceutical formulations. Importance of accelerated stability study.

• Degradation pathways (Degradation by hydrolytic, oxidative, reductive, photolytic, etc) and stabilization methods for formulation.

• Stability indicating assays and its importance

Stability testing and dating of solid and liquid dosage forms:

• Different approaches for stability testing of solid and liquids, kinetic principles, physical and chemical stability testing of pharmaceutical dosage forms and packages. Stability issues for vaccines and biological products.

Unit-10 Pilot Plant Scale Up Techniques:

Significance of pilot plant scale up study and large scale manufacturing techniques (formula, equipment, process, stability and quality control) of some important dosage forms such as tablets, capsules, injections, liquid orals, semisolids, ophthalmic products, emulsions including multiple emulsions.