PHARMACOGNOSY

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

THEORY

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

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

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

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

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.1

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

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

a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

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

a) Paper electrophoresis
b) Gel electrophoresis
c) Capillary electrophoresis
d) Zone electrophoresis
e) Moving boundary electrophoresis
f) Iso electric focusing

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

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

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and

cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

ADVANCED PHARMACOGNOSY - I

THEORY

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In-situ conservation of medicinal plants.
2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.
3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following
   i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.
4. Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.
   a) Carotenoids – i) α and β – Carotene ii) Xanthophyll (Lutein)
   b) Limonoids – i) d–Limonene ii) α – Terpineol
   c) Saponins – i) Shatavarins
   d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
   e) Phenolic acids– Ellagic acid
   f) Vitamins
   g) Tocotrienols and Tocopherols
   h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
   i) Miscellaneous

5 Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

PHYTOCHEMISTRY

THEORY

1. Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:
    a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids.
    b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin.
    c) Steroids: Hecogenin, guggulosterone and withanolides
    d) Coumarin: Umbelliferone.
    e) Terpenoids: Cucurbitacins

2 Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.

3 Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave

assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4 Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.

5 Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C)

a. Carvone, Citral, Menthol
b. Luteolin, Kaempferol
c. Nicotine, Caffeine iv) Glycyrrhizin.

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INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

THEORY

1. Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.

2 Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export – Import (EXIM) policy, TRIPS.

Quality assurance in herbal/natural drug products.
Concepts of TQM, GMP, GLP, ISO-9000.

3 Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4 Testing of natural products and drugs: Herbal medicines – clinical laboratory testing. Stability testing of natural products, protocols.

5 Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

MEDICINAL PLANT BIOTECHNOLOGY

THEORY

1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

2 Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.

3 Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.

4 Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic

plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

5 Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.

ADVANCED PHARMACOGNOSY - II

THEORY

1. Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

2 Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.

3 Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

4 Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.

5 Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating

Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

INDIAN SYSTEMS OF MEDICINE

THEORY

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine

   Different dosage forms of the ISM.

   Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality.

   Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

2 Naturopathy, Yoga and Aromatherapy practices

   a) Naturopathy – Introduction, basic principles and treatment modalities.

   b) Yoga – Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

   c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

3 Formulation development of various systems of medicine

   Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization,

   Shelf life and Stability studies of ISM formulations.

4 Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry – GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.

5 TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU

HERBAL COSMETICS

THEORY

1. Introduction: Herbal/natural cosmetics, Classification & Economic aspects.

   Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

2 Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

3 Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :

   Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

4 Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.

Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.