

**Syllabus portion completed for BPH_C_802_T – Pharmaceuticals - IV Theory subject, before 13th March 2020 for
Final Year B. Pharm. Semester VIII CBCS Academic Year 2019-2020**

Sr. No.	Details
1	Introduction to sterile dosage forms - Parenteral products
1.1	Various routes of parenteral administration, pyrogens, vehicle, Water for Injection (WFI) - preparation, purity, storage and distribution, vehicles other than WFI, additives in parenteral products.
1.2	Containers - glass and plastics- types and evaluation, rubber closures – characteristics and testing.
1.3	Personnel, Manufacturing facilities- layout, environmental control, cleanliness classes, air handling (HVAC systems), HEPA filters, laminar flow
1.4	SVP: formulation considerations- solutions, suspensions, product procedures, freeze drying.
1.5	LVP – types, formulation aspects, packaging, FFS technology.
1.6	QA & QC- sterility test, pyrogen/ endotoxin test, particulate evaluation, leaker test.
2	Ophthalmic Products
2.1	Physiology of eye, lachrymal system, tears, precorneal tear film, cornea, ocular bioavailability
2.2	a) Formulations - additives and packaging of various ophthalmic products - solutions, suspension, ophthalmic ointments and gels, preservatives and efficacy test b) Contact lens solutions: types of lenses, cleaning solution, disinfection solution, lubricants, multipurpose solutions and packages
2.3	QA and QC - sterility test, clarity, particle size for suspension, tests on ointments and collapsible tubes
3	Oral sustained and controlled release systems
	Need, definitions, Advantages of SR & CR systems, biopharmaceutical considerations; Properties of drug with reference to the design of oral SR systems Dose calculation of drug, calculation for dose- loading and maintenance
3.2	Matrix and reservoir type of systems, dissolution-controlled systems, diffusion-controlled systems, ion exchange-controlled systems
3.3	Evaluation of sustained release systems
4	Microencapsulation
4.1	Definition, need/ reasons, concepts of core and coat
4.2	Methods of microencapsulation - phase separation coacervation (various techniques), Wurster process, spray drying and related processes, interfacial polymerization, multiorifice centrifugal process, pan coating, solvent evaporation; extrusion & spheronization, Evaluation of microcapsules
5	Introduction to Industrial Pharmacy
5.1	Pilot plant scale up techniques: Need, components, Factors considered while scaling up of formulations: Mention the points for tablets, liquids (suspension, solutions, emulsions) and semisolids
5.2	Validation: Definition, Types- Prospective, concurrent, Retrospective and revalidation. Qualification of equipment-design, installation, operational, performance
5.3	Factory Layout: schedule M - general considerations/ steps, Examples of Typical layout schemes for Tablets, capsule, liquids, sterile formulations manufacturing areas
6	Introduction to NDDS
6.1	Advantages of NDDS, concept of targeting-Active & Passive targeting
6.2	Concept, design and one suitable application of a typical system of following NDDS: a) Floating gastro-retentive systems, b) Colon targeted drug delivery systems, c) Mucoadhesive drug delivery systems, d) Osmotic systems, e) Transdermal DDS (membrane permeation systems), f) Ocular inserts, g) Colloidal DDS (liposomes, nanoparticles, microemulsions)
7	Introduction to Pharmacokinetics
7.1	Definitions: Pharmacokinetics, ADME, bioavailability absolute and relative, bioequivalence. Emphasis on the importance in drug discovery, development and clinical pharmacy
7.2	Pharmacokinetics: Introduction to compartmental and physiological models. Introduction to the one compartmental open model and its assumptions

Syllabus portion completed for BPH_C_801_T – Pharmaceutical Chemistry III Theory subject, before 13th March 2020 for Final Year B. Pharm. Semester VIII CBCS Academic Year 2019-2020

No.	Details
	Discussion of the following classes of drugs including classification, chemical nomenclature, structure including stereochemistry, generic names, SAR and metabolism, molecular mechanism of action, synthesis(*) and rational development if any
1	CNS Drugs
1.1	Sedatives – Hypnotics Benzodiadepines: chlordiazepoxide, diazepam, nitrazepam*, temazepam, alprazolam, estazolam; zolpidem, eszopiclone, ramelteon (last 3 for self study – 1 hr).
1.2	Anticonvulsants Types of seizures (Self study- 1 hr) phenytoin, mephenytoin, ethotoin, trimethadione, diazepam, clonazepam, carbamazepine*, valproic acid, vigabatrine, progabide, lamotrigine, tiagabine
1.3	Antidepressants imipramine*, chlorimipramine, amitriptyline, nortriptyline, doxepine* fluoxetine*, paroxetine, sertraline, escitalopram, amoxapine
1.4	Anxiolytics Oxazepam, buspirone
1.5	Antipsychotics chlorpromazine*, triflupromazine, thioridazine, fluphenazine, trifluperazine, chlorprothixen(self study), droperidol , pimozide, risperidone, loxapine, clozapine, sulpiride
1.6	Antiparkinson's carbidopa, levodopa, selegiline, amantadine, bztropine, procyclidine, orphenadrine (last 3 for self study- 1 hr)
2	ANS Drugs
2.1	Adrenergic Drugs Alpha adrenergic agonists: phenylephrine*, naphazoline, xylometazoline, oxymetazoline, methyl dopa, clonidine, guanabenz, guanafacine Beta agonists : Isoproterenol, colterol, metaproterenol, terbutaline*, albuterol, isoxxsuprine, ritodrine Alpha antagonist : tolazoline, phentolamine, phenoxybenzamine, prazosin, doxazosin Beta Antagonists : pronethalol, propranolol*, sotalol, timolol, atenolol, metoprolol, esmolol, acebutolol, carvedilol, labetalol* (last two for self study, including synthesis of labetalol) Other adrenergic agents (Self study-2 hrs) : pseudoephedrine, ephedrine, guanethidine, propylhexedrine, reserpine
2.2	Cholinergic Drugs Muscarinic agonists : methacholine, carbachol, bethanechol, pilocarpine Acetylcholineesteraseinhibitors : physostigmine, neostigmine*, pyridostigmine, edrophonium, echothiophate, malathion, parathion, pralidoxime AntiAlzheimer's : Tacrine*, donepezil, rivastigmine
	Cholinergic antagonists : Atropine, scopolamine, homatropine, ipratropium cyclopentolate*, dicyclomine*, bztropine, procyclidine, isopropamide, tropicamide Neuromuscular blockers :(Self study) tubocurarine, gallamine, succinylcholine, decamethonium
3.	Analgesic Drugs
3.1	Opioid peptides(Self study) Different types of opioid receptors, Potuguese and Becket Casy model, agonists, partial agonists and antagonists of these receptors Morphine, codeine, levorphanol, buprenorphine, phenazocine, pentazocine, meperidine*, alpha and beta prodine, pheniridine, anileridine, fentanyl, methadone, dextropropoxyphene*, tramadol, nalorphine, naloxone, naltrexone, flupirtine Antidiarrhoeals (Self study-1 hr) : loperamide, diphenoxylate
3.2	NSAIDS paracetamol, aspirin, indomethacin, sulindac, mefenamic acid, ibuprofen, naproxen*, nabumetone, diclofenac*, piroxicam*, nimesulide, celecoxib, valdecoxib. Cytokine inhibitors :(Self study-1 hr) infliximab, rituximab, anakinra, abatacept Drugs in Gout : colchicine, probenecid, sulfinpyrazone, allopurinol, febuxostat
4	Drugs affecting Male and Female Health (Steroids)

4.1	Testosterone, 17-alpha-methyltestosterone, oxymesterone, fluoxymesterone, stanozolol, danazol (Self study) estradiol, ethinyl estradiol, mestranol, medroxyprogesterone acetate, megestrol acetate, norethindrone, norgestrel, diethylstilbestrol*(Synthesis for self study), clomiphene (Self study), tamoxifen, anastrozole, letrozole, exemestane (Self study-1 hr) medroxy progesterone acetate, megestrol acetate, norethindrone and norgestrel
4.2	Adrenocorticosteroids cortisone, hydrocortisone, prednisone, prednisolone, dexamethasone and betamethasone, flurometholone, fluocinolone, triamcinolone, aldosterone, fludrocortisone

**Syllabus portion completed for BPH_E_806_T – Phytopharmaceutical Technology Theory subject, before 13th
March 2020 for Final Year B. Pharm. Semester VIII CBCS Academic Year 2019-2020**

No	Topics
1	<p>Introduction to the terms Phytopharmaceutical Technology – Phytopharmaceuticals, Active ingredient, Botanical Drug Substance, Ethnomedicine, Herbal Medicine, Phytomedicine, Phytopharmaceutical Science, Regulatory affairs, Traditional medicine, Folklore medicine, Herbal medicine, Finished herbal product, Pharmaco-vigilance of herbals, Phytopharmacoepidemiology and Phytopharmacoeconomics.</p>
2	<p>Herbal Extracts Processing and authentication, Introduction to Preparation and Types of extracts with suitable examples – liquid, solid, semisolid, dried and powdered Large scale industrial method for preparation of extracts, Process and equipment: Names of equipment and their uses, merits and demerits in the unit operations of size reduction, Extraction, Filtration, Evaporation/ Distillation, Drying of Extracts</p>
3	<p>Formulations and drug delivery system A) Methods of preparations and evaluation of Herbal Tablets, Capsules, topical and liquid oral dosage forms. Study of any two examples of formulations under each dosage form with respect to their formulae and activities / claims of each ingredient used in them. B) NDDS of Herbal medicine: Limitation of Conventional, Challenges in Development of NDDS of Herbal medicine, Phytosomes, Nanocarriers, Transdermal with one example each. Use of Bio- enhancers in formulation development of herbal products. Labeling of Phyto-pharmaceuticals. Preservation of Phyto-pharmaceuticals</p>
4	<p>Quality Assurance and Quality Control of Phytopharmaceuticals A) For Herbal Extracts: Q.A by cultivation and Breeding, Standardized extracts –Quantitative standardization using different types of Marker Compound. Stability testing of Herbal extracts. B) For Formulations: Stability of herbal formulation, Bioavailability of Phytoconstituents from Herbal Formulations – Factors affecting bioavailability and pharmacokinetics of some herbal drugs and phytoconstituents.</p>
5	<p>Herbs as Phytopharmaceutical Products Occurrence, Structure, Pharmacology, Metabolism and Pharmacokinetics, Therapeutic uses, Recommended doses and Marketed preparations, Toxicity and Regulatory status of the following – Ephedra Alkaloids, Ginger, Garlic, Kava kava, Ginkgo Biloba, Valerian, Chamomile, Echinacea, Panax Ginseng, Cranberry, Acoruscalamus, Comfrey, Tomato, Liquorice, Senna, Cascara.</p>
6	<p>Non-Nutritive Sweeteners from Natural sources Preparation, evaluation and salient features of Steviosides, Thaumatin, Glycyrrhizin.</p>
7	<p>Herbal Cosmeceuticals Role of Herbs and phytoconstituents in the following categories of cosmetic preparations. Formulation aspects of the following cosmetic preparations and their market potential</p> <ul style="list-style-type: none"> • Skin cosmetics –herbs used as • Fairness agents- Turmeric (Curcumin), Uvaursi (Arbutin) Moisturizers – Aloe vera (mannans), Coriander seed oil (SELENOL)
	<p>Anti-ageing agents- Rose and rosehip (Rosa canina), Chamomile (Matricariachamomilla) Face packs -Apricot, Orange peel</p> <ul style="list-style-type: none"> • Colour cosmetics advantages of natural dyes and colourants– Onosmaechioides, Carthamine, Bixin - their use in lipsticks, rouges, eye shadows • Cosmetic products for eyes – Butcher’s broom, Chamomile • Hair cosmetics – <p>Colouring of hair- Tea extracts, Amla, Henna Herbs used in improving health of hair -shampoos, oils, conditioners. (Any two examples)</p> <ul style="list-style-type: none"> • Dental hygiene Products: Salvadorepersica, clove, neem
8	<p>Industrial production and estimation of the following phytoconstituents Preparation of their derivatives and products Alkaloids -Berberine Carotenoids- Capsanthin Flavonoids- Naringenin, Hesperidin Terpenoids- Citral, Forskolin, Gymnemic acid Steroids -Diosgenin Carbohydrates-Pectin</p>

**Syllabus portion completed for BPH_E_807_T – Clinical Pharmacy Theory subject, before 13th March 2020 for
Final Year B. Pharm. Semester VIII CBCS Academic Year 2019-2020**

No.	Details
1	Introduction to Clinical Pharmacy: Concept of Clinical Pharmacy, Community pharmacy and hospital pharmacy (Definition, scope and objectives)
2	Pharmacist-Patient Interaction
2.1	Patient Counselling: Role of Pharmacist in patient counselling
2.2	Patient Compliance, Methods of assessment of compliance, Reason for patient noncompliance, Strategies to improve compliance, Precaution and directions for medication, Administration instructions
3	Adverse Drug reactions: Epidemiology, Classification, Risk factors, Monitoring, Detecting and reporting of ADR
4	Drug interactions: Types, General Considerations and Mechanisms
5	Drug use in special population
5.1	Drugs used in Geriatrics
5.2	Drugs used in Paediatrics
5.3	Drugs used in Pregnancy
6	Therapeutic Drug Monitoring: Definition, indications and strategies
7	Drug discovery & development
7.1	Preclinical development
7.2	Clinical development-
	a. History, terminologies, types of clinical research, phases of clinical trials, role of clinical trial in new drug developments. Ethical issues in clinical trials: Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Independent Ethics Committee, Institutional Review Board)
7.3	Good Clinical Practice (GCP): Concept and importance
7.4	Definitions of essential documents; SOP, protocol, Investigator's brochure,
7.5	Introduction to BA/BE studies
7.6	Pharmacovigilance: Definition, scope and aims of Pharmacovigilance
8	Pharmacoepidemiology: Definition, types, methods, factors affecting drug utilization, applications of pharmacoepidemiology
9	Pharmacoeconomics and outcomes Research: Theories and methodologies of pharmacoeconomics and outcomes research, applications to pharmacotherapy and managed health care

Syllabus portion completed for BPH_C_803_L – Pharmaceutical Chemistry Lab II , before 13th March 2020 for Final Year B. Pharm. Semester VIII CBCS Academic Year 2019-2020

Synthesis of the following Drugs and Drug Intermediates

1. Synthesis of Benzilic Acid: Conventional Method and Green Modification as in Green Chemistry DST Monograph
2. Three Component Synthesis of Pyrimidone using Ethylacetoacetate, Benzaldehyde and Urea as per Green Chemistry DST Monograph
3. Hofmann rearrangement: Anthranilic acid from Phthalimide.
4. Reduction reaction: PABA from *p*-nitrobenzoic acid.
5. Pechmann condensation for coumarin synthesis using clay catalyst (Clay catalyzed solid state synthesis of 7-hydroxy-4-methylcoumarin).
6. Synthesis of resacetophenone (Ref. Vogel page 983)
7. Synthesis of 4-methylcarbostyryl (old syllabus experiment)
8. Synthesis of Phenytoin
9. Synthesis of Hippuric Acid.

Syllabus portion completed for BPH_C_804_L – Pharmaceutics Lab IV, before 13th March 2020 for Final Year B. Pharm. Semester VIII CBCS Academic Year 2019-2020

No.	Details
1	Preparation & Testing of WFI as per IP
2	Processing and monographic testing of Glass containers and rubber closures as per IP.
3	Preparation and documentation of the following injections: a. Calcium Gluconate injection IP b. Ascorbic acid injection IP. c. Sodium chloride & Dextrose Injection IP
4	Preparation and documentation of following ophthalmic products: a. Sulphacetamide eye drops, IP b. Official antibiotic eye ointment (any one)
5	Preparation and <i>in vitro</i> release evaluation of sustained release oral tablets (matrix type)
6	Dissolution testing of marketed formulations of conventional tablets containing poorlywater soluble drug (selection of medium)
7	Calculations of pharmacokinetic parameters -i.v. administration (plasma samples provided).
8	Microencapsulation of solid/liquid core using phase separation coacervation technique
9	Preparation and evaluation of mucoadhesive buccal formulation (tablet/film)
10	Validation of process- mixing/milling
11	Assignment on SOP's of dissolution apparatus/tablet press/coating equipment
12	Assignment on excipient/API specifications. (One example of each)