DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY

CIRCULAR NO. ACAD / PHARM. / 07 / 2006-007

It is hereby notified for the information of all concerned that, on the recommendations of the Ad-hoc-Board in Pharmacy and Faculty of Engineering & Technology, the Academic Council at its meeting held on 21-06-2006 has accepted the **Revised Structure of First, Second, Third & Forth Year B. Pharmacy Course and syllabus of First Year B. Pharmacy** as per Appendix-'A' enclosed with this Circular.

This is effective from the academic year 2006-007 onwards.

All the concerned are requested to note the contents of this Circular for their information and necessary action.

University Campus,
Aurangabad-431.004.

REF.NO.ACAD/PHARM./2006/
-6199-6203
Date:-28-06-2006

Director,
Board of College and
University Development.

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Copy of this circular is forward with compliments to:-

1] The Principals of all affiliated Pharmacy Colleges.

Copy to :-

1] The Controller of Examinations,
2] The Assistant Registrar, [Examination].
3] The Assistant Superintendent, [Engineering Unit Exam].
4] The Record Keeper.

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DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD.

REVISED SYLLABUS

BACHELOR OF PHARMACY

(B.PHARM.)

THIRD YEAR

[Effective from – June-2008 onwards]

Dr. Babasaheb Ambedkar Marathwada University, Aurangabad.

THIRD YEAR B.PHARM SYLLABUS

SUBJECT INDEX

THIRD YEAR B. PHARM

Sr. No.	Subject	Theory Hours per week	Practical Hours per week
3.1	Pharmaceutical and Cosmetic Technology	3	3
3.2	Pharmacognosy-II	3	3
3.3	Medicinal Chemistry-I	3	3
3.4	Pharmacology & Toxicology	3	3
3.5	Biopharmaceutics and Pharmacokinetics	2	...
3.6	Pharmaceutical Analysis-II	3	3
3.7	Biotechnology	3	...
TOTAL		**20**	**15**

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Equivalence of students who have passed/ failed ATKT at S.Y.B.Pharm Old Course syllabus and admitted to Third Year B.Pharm. New Revised Course 2008-09 onwards.

These students will have to appear and pass the subjects of Pharmaceutical Engineering and Organic Chemistry II before seeking admission to Final Year B.Pharm.

3.1 P'ceutics

(3)

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Subject: Pharmaceutical and Cosmetic Technology Class: B.Pharm.III year 75 HRS

S.No.	Topic	Content	Hours
		SECTION-A	
1	Tablet	Definition, Types (Compressed, effervescent, Fast dissolving, Chewable, Entric coated, Lozenges) Formulation components & Commonly used materials for enlisted types only). Granulation & Compression principle/theory, process including equipments Packaging operation & packaging equipments Defects in tablets	7
2	Tablet coating	Need & problems, Types (Sugar, Film, Enteric & Dry) Coating Materials Coating equipments Coating procedure Coating evaluation Defects in coating and its remedies	3
3	Palletization techniques	Need Extrusion & spheronization, cryopalletization, balling, melt spheronization	1
4	Capsules	Hard and Soft Gelatin Capsules: Types of capsules Composition & QC of empty shell Capsule formulation components Filling equipments & operation Defects in capsules and Quality Control .	3
5	Microencapsulation	Definition, Need, Fundamental consideration Methodology (Air suspension, Coacervation phase separation, Multiorifice centrifugal, Pan coating, solvent evoporation, spray drying & spray congealing)	3
6	Liquids	Clear liquid (Formulation consideration, Manufacturing, Stability of liquids) Emulsions (Theoritical consideration, formulation, evaluation of suspension) Suspensions (Theory of emulsion, formulation, equipment and stability of emulsion system)	4
7	Semisolids	Ointment, paste, creams: Percuteneous absorption, Raw material & types of vehicles, preservation Gels and Jellies: Gel microstructure, physical properties of gels and jellies, gel formiing substances and their pharmaceutical uses. Suppositories: Factors affecting drug absorption from rectal route, manufacture of suppositories, specific problems in formulating suppositories, testing of suppositories. (bases in brief)	4 2 1
8	Aerosols	Definition, Advantages, limitations, Types, Components (Propellents & Concentrate), Package (Container, valve, dip tube, actuator), Manufacturing, Quality control	2
9	Sterile products	**Small volume** History of parentrals, Classification of sterile dosage forms, General requirements Formulation components for solution, reconstituted product, suspensions, emulsions and depots Manufacturing (Site selection, Design concept, personnel and environmental control, HVAC system), Manufacturing flow and equipments involved) Materials (Glass, plastics & rubber), Processing of packaging material and SVP parentral packaging operation Brief discription of fundamental QC test of sterility, pyrogen, particulate matter & leakage including compendial requirements	9

3.1 P'ceutics

S.No.	Topic	Content	Hours
		SECTION-B	
		Large volume Legal status of LVP, Types of LVP used in clinical practices Formulation requirements and commonly used materials Process flow sheet of LVP, Sterilization process, introduction of form fill seal teachnology. Packaging material and operation of LVP Brief description of fundamental QC test of sterility, pyrogen, particulate matter & leakage including compendial requirements	5
		Opthalmics Anatomical & physiological considerations of opthalmic products, Types including solution, suspensions, ointments & occuserts, Formulation requirement, Components	2
		Blood products Whole human Blood - Collection, blood clotting phenomenon, anticogulatnts in blood collection & Storage, Blood components (Concentrated human RBC, Dried human plasma, Dried human serum, liquid palsma & serum, human plasma protein fraction, human fibrinogen, human fibrin foam) - Manufacturing, QC & uses, Plasma substitutes & expanders	4
10	Cosmetics	**General principle of formulation, Manufacturing and evaluation of following preparations):** **Skin** Skin Creams: Classification, formulation and evaluation of creams hand and body lotion, Lipstick, Powders, Rouge, antiperspirants & deodorants, sunscreen & suntans	12
		Hair Depilatories, shaving preparations, Shampoos, Colourants, Eye makeups, Fixers	8
		Dental Dentrifrices & other dental preprations	3
		Nails Nail paints, lacquers,Nail paint removers	2

Subject: Pharmaceutical and Cosmetic Technology (Practical) Class: B.Pharm.III year 3hrs/week/batch

List of Practicals

S.No.	TITLE
1	To prepare & evaluate tablet of paracetamol by wet granulation
2	To prepare & evaluate capsule formulation of an appropriate drug.
3	To prepare & evaluate aspirin tablet by dry granulation.
4	To perform Dissolution test of paracetamol tablet
5	To prepare and evaluate dispersible tablet of nimesulide/appropriate drug
6	To demonstrate Sugar coating process of given tablet.
7	To demonstrate Film coating operation of given tablet.
8	To prepare transparent topical gel of diclophenac diethyl ammonium/appropriate drug
9	To prepare and evaluate salicylic acid ointment.
10	To prepare & evaluate Lactocalamine suspension
11	To prepare & evaluate Liquid paraffin emulsion
12	To perform Microbial count of aseptic area in filling zone
13	To prepare & evaluate Calcium gluconate injection
14	To prepare & evaluate Ascorbic acid injection
15	To demonstarate of Pyrogen test
16	To evaluate given sample of glass as packaging material.
17	To evaluate given sample of plastic as packaging material.
18	To study preservative sorption ability of rubber closure.
19	To prepare & evaluate Cold cream
20	To prepare & evaluate Vanishing cream
21	To prepare and evaluate Shampoo

S.No.	Topic	Content	Hours
22	To prepare and evaluate Lipstick		
23	To prepare and evaluate Depilatory		
24	To prepare and evaluate Suppository of an appropriate drug		
25	To prepare and evaluate Microencapsule using phase separation coacervation method		
26	To prepare and evaluate Microencapsules using solvent evaporation method.		
27	To prepare and evaluate Toothpaste		
28	To prepare and evaluate Nail lacquer		

References

Indian Pharmacopoeia (Latest edition)
British Pharmacopoeia (Latest edition)
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Pharmaceutical dosage forms: Tablets, Herbert A Lieberman, Leon Lachman and Joseph B Schwartz, Vol II, 2nd edition, Marcel Dekker, INC, New york, 1989.
Pharmaceutical dosage forms: Tablets, Herbert A Lieberman, Leon Lachman and Joseph B Schwartz, Vol III, 2nd edition, Marcel Dekker, INC, New york, 1989.
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Encyclopedia of Pharmaceutical Technology, James Swarbrick, James C Boylan, Vol 5, Marcel Dekker, Inc, New York, 1992.
Encyclopedia of Pharmaceutical Technology, James Swarbrick, James C Boylan, Vol 6, Marcel Dekker, Inc, New York, 1992.
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The Theory and Practice of Industrial Pharmacy, Leon Lachman, Herbert A Lieberman, Joseph L Kanig, 3rd edition, Varghese Publishing House, Mumbai, 1987.
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Harry's Cosmeticology, JB Wilkinson, RJ Moore, 7 th edition, Longman Scientific and Technical, England, 1982.
Cosmetology- Theory and Practice, Karlheinz Schrader, Andreas Domsch, Verlag fur chemische Industrie, Augsburg, Vol I, 2005.
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A Hand Book of Cosmetics, BM Mithal, RN Saha, Vallabh Prakashan, Delhi, 2000.
Sterile Dosage Forms , S.J.Turco, Third edition, Lippincott Williams and Wilkins, Philadelphia 1987.
Cosmetic technology, Sanju Nanda, Arun Nanda, Roop Khar, Birla Publications Pvt. Ltd, Delhi

3.2 P'Cog-II

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Class: Third B. Pharm.

Subject: Pharmacognosy II (Theory) **(3 lectures/ week)**

SECTION- A

1. Overview of traditional and herbal medicine, introduction to phyto-pharmaceuticals, different classes of active constituents namely: Primary metabolites such as carbohydrates, proteins, lipids, secondary metabolites such as alkaloids, glycosides, resins, tannins, volatile oils etc.

(04 hrs)

2. Detailed study of each category of drugs under pharmacognostical & phyotochemical scheme including biosynthesis. **(04 hrs)**

3. **CARBOHYDRATES AND RELATED COMPOUNDS:** **(12 hrs)**

Biological source, method of production, chemical constituents, tests, uses, biosynthesis and adulterants of following drugs:

a. Starches and modified starches:

Maize, wheat, rice, bran, arrowroot, dextrin and cyclodextrin

b. Gums and Mucilages: Detailed study of following gums:

Guar gum, loucust bean gum, acacia, tragacanth, ghatti, karaya, sterculia, alginates, alginic acid, agar, carracenans, isapgol, psyllium, pectins.

c. Cellulose and Cellulose derivatives

Manufacturing of absorbent cotton and non-absorbent cotton, wood cellulose and their derivatives.

4. **LIPIDS:** **(10 hrs)**

a. Definition and method of extraction, chemistry and method of analysis
b. Study of method of production, chemical constituents, tests uses, biosynthesis and adulterants of following:

i) Castor oil ii) arachis oil iii) olive oil iv) almond oil v) cod liver oil vi) shark liver oil vii) Chaulmoogra oil viii) wool fat

ix) lanolin x) bees-wax xi) spermaceiti xii) cocoa butter

5. **PROTEINS AND ENZYMES** **(10 hrs)**

a. Definition, classification, chemistry, methods of extraction of gelatin, collagen and its related products.
b. Study of following protein containing drugs, their biological source, chemical constituents, biosynthesis and pharmaceutical importance:

i) malt extract ii) protamine sulfate iii) heparin iv) collagen

v) gelatin vi) caesin vii) yeast viii) levodopa(kawach)

SECTION-B

1. GLYCOSIDES: **(15 hrs)**

Definition, sources, classification general properties general method of isolation estimation, diagnostic characters, chemistry chemical nature biosynthesis adulterants and uses

a. cardiac glycosides: Digitalis, strophanthus, squill, thevetia
b. anthracene glycosides: Senna, aloe, rhubarb, cascara
c. Saponin glycosides: dioscorea, asparagus, solanum species, safed musali, liquorice, quillaia bark, brahmi, bitter gourd, genseng, senega.
d. cyanogenetic glycosides: wild cherry bark, bitter almond
e. Isothiocyanates glycosides: mustard
f. Bitter glycosides: kalmegh, chirata, picrorhiza
g. Coumarin glycosides: psroalea, visnage, ammi, tonka bean
h. Flavonoid glycosides: buck wheat, orange peel, lemon peel, silymarin, and gingko.
i. Aldehyde glycosides. vanilla
j. Phenol glycosides: bearberry.

3.2 P'Cog-II

2. RESIN AND RESIN COMBINATION: **(08 hrs)**

a) Definition, classification, properties, sources, diagnostic chararcters, active constituents, uses and adulterants.

b) Method of production and study of biosynthetic pathways.

colophony, myrrh, benzoin, storax, balsum of tolu, balsum of peru, jalap, asafoetida, shellac, ammonicum, copaiba, ginger, gomboge, terpentine.

3. TANNINS: **(08 hrs)**

Definition, properties, classification, general method of isolation, estimation, uses, adulterants along with biosynthesis of the following class of drugs:

i) Catechu ii) tannic acid iii) nut galls iv) ashoka v) arjuna

vi) behera vii) myrobalans

4. MINERAL DRUGS: **(02 hrs)**

Study and pharmaceutical importance of following mineral drugs:

Asbestos, bentonite, calamine, chalk, fullersearth, talc, shilajit and mica.

6. NATURAL FIBRES: **(02 hrs)**

Detailed study and pharmaceutical importance of following natural fibers:

Cotton jute, hemp, silk, wool

3.2 PCog-II

Pharmacognosy II (Practical)

3 hours / week / batch

1. Introduction of microscope and their handling.
2. Morphological characters of plant families mentioned in theory
3. Morphological and histological study of following plants:

   Senna, wild cherry bark, asparagus, kalmegh stem, glycerrhiza, digitalis, ginger and capsicum.

4. Identification of following unorganized drugs by chemical test and morphological characters:

   Asafetida, myrrh, guggul, shellac, benzoin, gelatin, colophony, acacia, tragacanth, sterculia, ghatti, aloes, agar, bentonite, keisulguhr

5. Quantitative microscopy (minimum 5 practicals)

   - Measurement of starch grain, calcium oxalate crystals, and phloem fibres in powder crude drug
   - Determination of stomatal number and stomatal index of leaf drug
   - Determination of vein islets and vein termination number of leaf drug
   - Determination of palisade ratio of leaf drug
   - Determination of moisture content, ash value and extractive value of crude drug (minimum 3 practicals)

6. Test for identification of adulterants in

   Castor oil, arachis oil, shark liver oil, wool fat, bees wax.

7. Analysis of fats and oils

   Iodine value, saponification value, acid value, ester value

8. Identification of fibers: cotton, jute, hemp, silk and wool.

9. Preparation of herbarium sheets of at least twenty (20) medicinal and aromatic plants, which are locally available.

10. Live demonstration of medicinal plants at the medicinal plant garden/ Biodiversity hotspot/ herbal drug industry.

3.2 P'Cog-II

Recommended books:

1. Kokate C.K Purohit A.P and Gokhale S.B, Pharmacognosy, Nirali Prakashan.
2. Kokate C.K Practical Pharmacognosy, Vallabh Prashan, Delhi.
3. Atal C.K and Kanpur B.M Cultivation and Utilization of Medicinal Plants, RRL, Jammu.
4. Brain K.R and Turner T.T, The Practical Evaluation of Phytopharmaceuticals, Wright-Scientechnica, Bristil.
5. Miller I.P Phytochemistry, 1-3 Van Nostrand Reinhold Co.
6. Nadkarni A.K Indian Materia Medica, 1-2, Popular Prakashan Pvt. Ltd. Bombay.
7. Official Methods of Analysis, Association of Official Analytical Chemists Publications, Washington.
8. Peach K, And Tracey M.V, Modern Methods of Plant Analysis, 1-4 Narosa Publishing House, New Delhi.
9. Swain.T, Comparative Phytochemistry, Academic Press London.
10. Trease, G.E and Evans W.C Pharmacognosy, 12th edition, Bailliere tindal, Eastbourne, UK.
11. Wallis, T.E Analytical Microscopy, J.A Churchill limited, London.
12. Wallis, T.E Textbook of Pharmacognosy, J.A Churchill limited, London.
13. Whistler R.L, Industrial Gums, Polysaccharides and their Derivatives, 2nd edition Academic press, New Delhi.
14. Tyler, V.E, Brady,R.,Pharmacognosy.
15. Wagner, S.B., Zgainsky, Plant Drug Analysis.
16. V.D. Rangari, Pharmacognosy and Phytochemistry, Vol.1 & 2.
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24. Herbal Pharmacopoeia of India, Govt. of India. Ministry of Health. vol 1 & 2. (1998 and 2001)
25. Ashutosh Khar, Pharmacognosy and Pharmaco-biotechnology, New Age International Publishers.
26. S.H Ansari, Essentials Of Pharmacognosy, CBS Publishers, New Delhi.
27. Kaliya, Textbook of Industrial Pharmacognosy, CBS Publisher, New Delhi.
28. S.V Bhatt, Chemistry of Natural Products, Narosa Publishing House, New Delhi.
29. O.P Agrawal, Chemistry Of Organic Natural Products, Vol 1 & 2
30. Indian Herbal Pharmacopoeia, Indian Drug Manufacturers Association, Mumbai. (New Edition, 2002)

31. Quality Standards Of Indian Medicinal Plants, Vol I – 8, Indian Council Of Medical Research, New Delhi.
32. Quality Control Methods For Medicinal Plant Material, WHO,Geneva, 1998.
33. WHO Monographs On Selected Medicinal Plants Vol 1 & 2, WHO, Geneva, 1999.

3.3 Med Chem I

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Class: Third B. Pharm.

Subject: Pharmaceutical Medicinal Chemistry I (Theory) **3 hrs. / week**

Section A

Sources of drugs: **(2 hrs.)**

Search for new drugs- serendipity, extraction from natural sources, Molecular modification (with example)

Theoretical aspects of drug action : **(4 hrs.)**

The Ferguson principle, Physiochemical parameter and pharmacological activity, solubility, partition coefficient, surface activity, pKa, ionization constant, steric factor, Stereochemistry and biological activity.

Drug Metabolism: **(4 hrs.)**

Metabolic process – Phase - I (Oxidation, Reduction, Hydrolysis). Phase – II (Glucuronide conjugation, Acylation, Methylation, Mercapturic acid formation, sulfate onjugation).

Factors affecting metabolism – Genetic factors, physiological factors, pharmaceutical factors and drug interactions.

Relationship of drug metabolism to drug design Including modification leading to shorter and longer duration of action.

Development of the following classes of drugs:

Synthesis, chemical nomenclature, classification (chemical and mode of action) and generic names, Structure activity relationship SAR), mechanism of action and uses of following drugs:

3.3 Med Chem I

Antituburcular and antileprotic drugs: **(4 hrs.)**

Para amine salicylic acid, isoniazid, pyrazinamide, ethionamide, ethambutol, Antituburcular antibiotics like, Rifampicin, Cycloscrine and Streptomycin, Dapsone and derivatives, Clofazimine.

Combination therapy in TB treatrment.

Antimalarials **(4 hrs.)**

Life cycle of parasite and drugs acting on the various stages, Cinchona alkaloids, Artemisine and its derivatives, synthetic antimalerials of following classes: 4-amino quinoline: chloroquine, amidoquine, sonotoquine, hydroxycholorquine.

8-aminoquinoline: primaquine, pamaqune, pentaquine, isopenataquine. 9-aminoacridine: quinacrine, mepacrine. Quinoline methanol derivatives: mefloquine, folic acid inihibitors, proguanil, pyrimethamine, trimethoprim, miscellaneous drugs like halofantrine.

Anthelmintics: **(4 hrs.)**

Trematode diseases (schistosomiasis)Lucanthone, Hycanthone, Niridazole Oxamniquine, praziquantel. Cestode diseases (tapeworm): niclosamide, Nematode infections: Onchocerciasis (river blindnessarb), Diethyl carbamazepine citrate, ivermectine, piperazine citrate. Gastrointestinal nematode infection: Benzimidazole like Mebendazole, Parbendazole, albendazole, pyrantel pamoate, levamisole.

Antiamoebics: **(2 hrs.)**

Life cycle of parasite, Ipecac alkaloids: Emetine stereochemistry, Metronidazole and Tinidazole, ornidazole, Diloxanide furoate, Quinfamide, Dihydroxyquinine, furazolidone.

Section B

Antibiotics: **(6 hrs.)**

B-lactam antibiotics: penicillins and cephalosporines, tetracyclines, macrolides, aminoglycosides polypeptides, polyenes, chlormaphenicol, Synthetic antibacterial agents: Fluoroquinolone, Ciprofloxacin, norfloxacine, nalidixic acid, sparfloxacin.

3.3 Med Chem I

Antifungal agents **(2 hrs.)**

All pathogenic fungi and their corresponding diseases. Antibiotics like amphotericin-B, nystatin, and Griseofulvin, Imidazole derivatives: miconazole, Ketoconazole, Fluconazole, clotrimazole, tolnafate.

Antivirals **(5 hrs.)**

Nucleoside derivatives like Idoxuridine, Vidarabine, Trifluridine, Acyclovir, Ganciclovir. Inhibitors of reverse trancriptase: Zidovudine (AZT) and Nevirapine. HIV protease inhibitors: Squnavir, Indinavir and ritonavir. Miscellaneous: amantadine, remantadine, envirxime, interferon and its properties.

Sulfonamides **(2 hrs.)**

Importance of pka in designing good sulfonamides, N1 and N4 substituted.

Synthesis of : sulphamethoxazole, Sulphadimidine, succinylsulphathiazole, sulphadiazine,

Antineoplastic agents **(6 hrs.)**

Problems face in cancer chemotherapy, alkylating agents, antimetabolites, antibiotics, plant products. Synthesis: chlorambucil, methotrexate sodium, mercaptopurine

Anticoagulants **(2 hrs.)**

Heparin, oral anticoagulants (coumarin analogues and 1.4 indanediones)

Dicoumarol and Warfarin sodium

S.N. Underlined drugs synthesis is mandatory.

3.3 Med Chem I

Practicals

(3 Hrs/Week)

Small-scale preparation of following compounds:

Cinnamic acid, Anthranillic acid, Benzillic acid, 8-hydroxy Quinoline, Benzhydrol, Benzanilide, orthochlorobenzoic acid, Benzylidine acetophenone, Acetanilide from acetophenone, Tetrahydrocarbazole, Azo dyes and synthesis of at least six active pharmaceutical ingredients (API's) wherein the synthesis of the intermediate or final products involve named reaction.

Practical involving the process of Recrystallisation, Steam Distillation, Vacuum Distillation and Catalytic Hydrogenation

Reference Books:

1. Lednicer- The Organic Chemistry of Drugs synthesis, Vol I-VI, John Wiley and sons.
2. Bergers' Medicinal Chemistry and Drug Discovery, 5th edition, Vol I-V, John Wiley & sons.
3. Wilson and Gisvolds', Textbook of Organic Medicinal and Pharmaceutical Chemistry, 11th edition, by John H. Block & John M. Beale Jr. Lippincott Williams and Wilkins.
4. William O. FOye, Principles of Medicinal Chemistry, 6th edition , Varghese publication (2003).
5. I.L. Finar, Organic Chemistry, 5th edition, Vol I-II. ELBS with Longmann (1995).
6. Bently and Drivers , Textbook of Pharmaceutical Chemistry, 8th edition, revised by I. M Atherden, Oxford (1996).
7. Gogte, Profiles in Drug Synthesis.
8. S.S. Kadam, K. R. Mahadik and Bothra K. G., Principles of Medicinal Chemistry, Vol I-II 5th edition, Nirali Prakashan.
9. Comprehensive Medicianl Chemistry by C. Hansch, Vol IV.
10. Inorganic Medicinal and Pharmaceutical Chemistry- J. H. Block, E. B. Roche, I. O. Soine, C. O. Wilson.
11. Modern Inorganic Pharmaceutical Chemistry C. A. Discher
12. Concise Inorganic Chemistry- J. D. Lee

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3.4 P & T

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Class: Third B. Pharm.

Subject: Pharmacology and Toxicology (Theory) 3 hrs. / week

S.N.	TOPIC	HRS
	SECTION A	
1.	**General Pharmacology:** Introduction, definition, history. Sources, Routes of administration. Absorption and the factors affecting them. Pharmacokinetics, Pharmacodynamics - Biological half-life, Bioavailability and bioequivalence, First pass effect, Drug accumulation. Mechanism of drug action - Molecular and bio-chemical, receptor concept and drug receptor interaction, Mechanism of signal transduction, Dose response relationship, Factors modifying drug effects. Drug interaction, Drug toxicity. Discovery and development of new drugs.	10
2.	**Pharmacology of autacoids and their antagonists**: Histamine, Serotonin, Ergot alkaloids, Vasoactive Peptides, Prostaglandins, Eicosanoids, Thromboxanes, Leukotrines, Nitric oxide etc.	8
3.	**Drugs acting on Autonomic Nervous system**: Organization and function of autonomic nervous system, Autonomic transmissions, co-transmissions their integration and relationships.	2
	Drugs acting on Cholinergic system: Cholinergic transmissions, biosynthesis, storage, release and hydrolysis of cholinergic neurotransmitters and cholinergic receptors. Parasympathomimetics agents and Parasympatholytic drugs.	6
	Drugs acting on Adrenergic system: Adrenergic transmission, biosynthesis, transmission, storage release, re-uptake and metabolism of endogenous catacholamine, adrenergic receptors. Sympathomimetics, sympatholytic and adrenergic neuron blockers. catacolanine deplitors. Dal's vasomotor reversal.	6
	Drugs acting on Autonomic ganglia: Ganglionic stimulants, Ganglionic blocking agents, Neuromuscular blocking agents.	3
	Screening of drugs belong to ANS category: Organization and general method of screening for Parasympatholytic, Sympatholytic, Sympathomimitics, Muscarinic agents, ganglionic blockers,	3
	SECTION – B	
4.	**Endocrine Pharmacology:** Hypothalamic and Pituitary hormone, Thyroid hormone, Adrenocortical hormones, Gonadal hormones, Pancreatic hormones, Parathyroid hormones. Oxytocics, antithyroid agents, hypoglycemic agents, corticosteroid antagonist, gonadal hormones inhibitors, oral contraceptives, antifertility agents, drugs regulating calcium homeostasis.	10

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3.4 P & T

S.N.	TOPIC	HRS
5.	**Chemotherapeutic Agents**: History, Basic concept. Bacterial resistance and mechanism of development of bacterial resistance. Sulfonamides, Trimethoprim and Quinolones, Antibiotics interfering with bacterial cell wall synthesis, protein synthesis DNA and RNA. Drugs used in treatment of Malaria, Tuberculosis and Leprosy, Helminthesis and Amoebiosis, Protozoa infections, Urinary tract infection, Sexually transmitted diseases, Skin diseases including fungal infections.	12
	Chemotherapy of cancer: Type, rational approaches of treatment, Developmental stages. Classification pharmacological account of drugs used as anticancer.	3
	Chemotherapy of HIV infection and AIDS: Classification, Pharmacological account for drugs used in treatment of HIV infection and other antiviral drugs. Pharmacotherapy of AIDS and its complications.	3
6.	**Immunomodulators:** Immuno-stimulants and depressants	2
7.	**Toxicology:** Basic principles of toxicology. Acute, sub acute and chronic toxicity. Local and systemic toxicity. Factors influencing toxicity. Mutagenicity, carcinogenicity and teratogenicity. Basic principles of management of toxicity. General treatment of poisoning. Management of poisoning due to drugs, chemicals, heavy metals.	7

References:

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- Bevan J.A., Thompson J.H., Essential of Pharmacology, Harper and Row Publishers, Philadelphia
- Craig C.R. and Stitzel R.E., Modern Pharmacology, Little Brown and Co, Bosten
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- Goldstein A., Aronow I., Kalman S.M., Principles of Drug action: The Basic of Pharmacology, A Wiley Biomedical Health Publications, John Wiley and Sons, New York

3.4 P & T

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- Laurence D.R. and Bacharach A.L., Evaluation of Drug activity, Pharmacometrics, Academic Press, London
- Pharmacopoeia of India (1985), Controller of Publication, Delhi
- Prashan S.N., Maickel R.P. and Dutta S.N., Pharmacology in Medicine-Principles and Practice, S.P.Press International Inc., Maryland
- Turner R.A., Screening Methods in Pharmacology, Academic Press, London
- Balaraman R., Gulati O.D, Patil P.N., Goyal R.K., Topics in History of Pharmacology, BS Shah Publications, Ahmedabad
- Bauer L.A., Applied Clinical Pharmacokinetics, McGraw-Hill Professional Singaapore
- Butterworth S.: Modis Textbook of Medical Jurisprudance and Toxicology
- DiPiro J.T., Encyclopedia of Clinical Pharmacology, Marcel Dekker, New York
- DiPiro J.T., Pharmacotherapeutics: A Pathophysiological Approach, Elsevier Publications, London
- Harisons: Principles of Internal Medicines, McGraw Hill Publications, Singpore
- Parikh C.K., Parikhs Text Book of Medical Jurisprudence and Toxicology, CBS Publicahers and Distributors, Mumbai
- Pradhan S.N., Maicjel R.P. and Dutta S.N.: Pharmacology in Medicine-Principles and Practice, S.P. Press Internaltional Inc, Maryland
- Speight T.M. and Holford N.H.G., Avery's Drug treatment, Blackwell Publishing, New York
- Tripathi K.D., Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi
- Dart Medical Toxicology, Third edition, Lippincott William and Wilkins
- Herfindal Gaureley, Text Book of Therapeutics: Drug and diseases management, Seventh edition, Lippincott William and Wilkins

3.4 P & T

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Class: Third B. Pharm.

Subject: Pharmacology and Toxicology (Practical) 3 hrs. / week / batch

1. Introduction, Need, scope and Experimental Pharmacology, Isometric and isotonic muscle contractions and their application in experimental pharmacology
2. Study for handling and working of commonly used laboratory wares in experimental Pharmacology (Sherington's rotating drum, Organ bath, Assembly stand, Recording lever and tumbers, cannula etc.)
3. Various basic techniques of experimental Pharmacology like euthanasia, isolation of tissues like heart, rectus muscle, recording of various types of contraction (Isotonic and isometric), recording procedures (smoking, resine fixing, pen recording etc.) setting and maintenance of assembly.
4. Care and handling of commonly used laboratory animals. Animal physiology, biochemical reference values in various animals.
5. Study of physiological salt solutions, drug solution, their preparation and storage, different strengths of solutions used in experimental pharmacology.
6. Study of various routes of drug administration using suitable animal.
7. Study of various methods for collection of blood, body fluids, urine etc. in various experimental animal (with demonstration using animal)
8. Study of various anesthetics used for laboratory animals.
9. Study of various computer aided software demonstrating various experiments in experimental Pharmacology - This study should not be used as replacement for animals experiment. (The computer aided software will act as training before actual animal experiment.)
10. To study the effect of change in ionic strength of Physiological salt solution on tissue response using suitable animal tissue.
11. To study the effect of change in temperature & pH on tissue response using suitable animal.
12. To study the effect of digitalis on hypodynamic failing heart
13. Recording of concentration response curve (CRC) of acetyl choline using suitable animal tissue
14. Recording of concentration response curve (CRC) of Histamine using suitable animal tissue
15. To study effect of esarine / Physostigmine on CRC of acetyl choline
16. To study effect of d-tubocurarine on CRC of acetyl choline
17. Study the drug synergism using suitable isolated tissue
18. Study the drug antagonism using suitable isolated tissue
19. To study the effect of drug on cilliary movement using suitable animal model
20. To study the effect of various drugs on sleeping time using suitable animal
21. To study miotic and mydriatic effect of drug using suitable animal (Demonstration)
22. To study the effect of vasocontrictor and vasodilatos on hind-limb perfusion of suitable animal.

3.4 P & T

23. Comment of given prescription with reference to case reports mentioning possible indications and contraindications with dose, route of administration, justification for inclusion of ingredients.
24. To study clonidine induced hypothermia (Demonstration)
25. To record the ECG of animal (Demonstration)

NOTE: The Principal, Head of Department and the subject in charge should look in the matter of utilization of animals for experimental Pharmacology Practical. The Institute should seek permission from CPCSEA (Registration) as per *The Prevention of Cruelty to Animals act of 1960, The Experiments on Animals (Control and Supervision) Amendment Rules (1998) and the Breeding of and Experiments on Animals (Control and Supervision) Rules (1998).* The protocols used for above experiments must be approved in IAEC (Institutional Animal Ethical Committee) meeting.

References:

- Burn J.H., Practical Pharmacology, Blackwell Scientific Co Oxford
- Ghosh M.N., Fundamental of Experimental Pharmacology, Scientific Book Agency, Bombay
- Jaju B.P., Pharmacological Practical Exercise Book, Jaypee Brothers, New Delhi
- Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, New Delhi
- Laurence D.R. and Bacharach A.L., Evaluation of Drug activity: Pharmacometritics, Academic Press, London.
- Perry W.L.M., Pharmacological Experiments on Isolated Preparations E & SP Livingston.
- Sheth U.K., Dadkar N.K. and Kamat U.G., Selected topics in Experimental Pharmacology, Kothari Book Depot, Bombay
- Turner R.A., Screening methods in Pharmacology, Academic Press, London
- Bolton, Sanford and Bon, Charles Pharmaceutical Statistics (Drug amnd the Pharmaceutical sciences: a series of Textbooks and Monographs), Dekkers, New Delhi
- Daniel Wayne W., Biostatistics: A fundamental for analysis in the health science, Wiley series in probability ans statistics, Wiley interscience, USA.
- Goyal R.K., Practical Experimental Pharmacology., BS Shah Prakashan, Ahmedabad.
- Patil C.R. X-Cology (Software), Pragati book Co. Pvt. Ltd.
- Ravindran R: X-Pharm (Software), Indian Journal of Pharmacology, JIPMER, Pondichery
- Tozer R., Clinical Pharmacokinetics, Wiliams and Wiljins Publications, New York
- Koppanyi T and karczmar A.G., Experimental Pharmacodynamics.
- Vogel's Drug discovery and evluation, Second edition, Springer
- V.G.Ranade, Shalini Pradhan, P.N.Joshi. A Text book of Practical Physiology, Fourth edition, Pune Vidyarthi Griha Prakashan, Pune

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3.5 Biopharm & P'kintecs

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Class: Third B. Pharm.

Subject: Biopharmaceutics and Pharmacokinetic (Theory) **2 hrs. / week**

Total hrs: 50

SECTION-A

Sr. No	Topic	References	Number of Hours
1	**Introduction**: Definition of absorption, distribution, metabolism, excretion, elimination, disposition, half life, first pass metabolism, entero-hepatic cycling, Bioavailability, Biopharmaceutics, pharmacokinetic, Pharmacodynamic, Bioequivalance, therapeutic and pharmaceutics equivalence and alternatives.	2,3,4	2
2	**Mathematical fundamentals in pharmacokinetic:** Common Log, natural log, rules of log, equation for straight line, semilogarthmic graph, unites in pharmacokinetic. Rates and order of reactions, Laplace transformation.	4,11	3
3	***Absorption:*** Physiology of GI tract, and cell membrane, Mayonnaise sandwich model and fluid mosaic model. *Mechanisms of drug absorption*: Passive diffusion, active transport, facilitated diffusion, Ion-pair transport, pore/paracellular transport, vesicular transport.	1,2,3,4,7	3
4	**Factors affecting Bioavailability:** *Biological factors:* Gastric emptying, GI pH, interaction with food fluid and normal GI constituents, malabsorption, diseased state, Blood flow to GI Tract, Drug Stability in GIT, etc. *Physicochemical Factors:* Effect of pH , Pka and lipophilicity of drug(pH partition hypothesis), Dissolution: Diffusion theory, surface renewal theory, limited salvation theory, Methods to enhance dissolution, Polymorphism, Salt formation, Hydrates /solvates complexation, adsorption, etc Introduction to Biopharmaceutical classification system. *Dosage form related factors:* role of dosage form,	1,2,3,4;7	9

	effect of processing variables and excepients on drug absorption		
5	**Methods of studying absorption**: Cell culture technique, tissue technique, artificial membrane, In situ-method, In vivo method, markers, Gamma scintigrapy study.	1,5,11	2
6	**Distribution:** Factors affecting distribution, Physiochemical properties, Physiological factors, Various barriers for drug distribution, miscellaneous factors like age, pregnancy, obesity, diet, diseased state and drug interaction. Apparent volume of distribution and its measurement.	1,2,3,4,7	4
7	**Plasma and tissue binding of drug:** components of blood binding to drug, factors affecting protein binding, binding of drug to other tissues, clinical significance of protein/tissue binding, effect on drug effect, distribution, elimination, Kinetics of protein binding.	2,3,4,	2
	SECTION-B		
8	**Elimination of drug**: principle processes in urinary excretion, factors affecting renal excretion, concept and estimation of clearance, organ clearance concept, hepatic clearance, factors affecting hepatic clearance, liver extraction ratio, blood flow limitations, entero-hepatic cycling and hepatic first pass metabolism. Introduction to other non –renal routes of excretion like salivary, mammary, pulmonary, skin/dermal, gastro-intestinal and genital excretion.	2,3,4,7	3
9	**Metabolism**; drug metabolizing organs, effect of Metabolism on drug activity, phase I and phase II pathways (no chemical reactions), enzymes in drug Metabolism, induction and inhibition of enzymes, factors affecting Metabolism.	2,3,4	2
10	**Dosage regimen**: Principal of superposition, design of Dosage regimen, dose size, dosing frequency, fluctuations, accumulation index, steady state concept, time required to reach steady state, loading dose, maintenance dose, Individualization of dosage in obese patients, neonates, infants, children, elderly patients in hepatic and renal failure.	2,3,11	3

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3.5 Biopharm & P'kintecs

11	**Pharmacokinetic models**: types pharmacokinetic models, physiological or perfusion model and non-compartmental model. Statistical moment theory.	2,3,4,10,11	2
12	**Compartment Model**: concept of central and peripheral compartments. Pharmacokinetic and mathematical treatment of one compartment open model (linear) IV bolus, IV infusion, and extra – vascular administration calculations of pharmacokinetic parameters. Sigma minus method, excretion rate method, methods of residuals, Wagner – Nelson method. Introduction to multi-compartmental behavior of drug (No mathematical treatment /derivations).	2,3,4,10,11	8
13	**Introduction to Pharmacodynamic**: Drug concentration and pharmacological response, therapeutic window, graded and quantal response, Pharmacodynamic models linear model, logarithmic model, E-max model, Onset, intensity and Duration of action –concentration relationship.	1,2,3,4	2
14	**Bioavailability and bioequivalance:** Absolute and relative, Bioavailability, purpose of Bioavailability study, protocol and study design for Bioavailability, wash out period, reference and test products, methods for estimation of Bioavailability: plasma data, urine data, Pharmacodynamic method, method for measurement of AUC, concept of IV-IVC relations.	2,3,4,7,11	3
15	**Non-linear pharmacokinetic: causes**/factors for non-linear behavior of drug, machaelies-menton equation, calculation of Km and Vmax.	2,3,7,11	2

Note: Numericals based on Pharmacokinetcs, bioavailability and bioequivalance Study (Similar type as given in Reference 3, 4 & 11)

REFERENCE:

1. "Principles and applications of Biopharmaceutics and pharmacokinetics " Dr. H.P.Tipnis and Dr. Amrita Bajaj, carrier publication
2. "Biopharmaceutics and pharmacokinetics: A treaties" Brahmankar D.M. and Sunil Jaiswal, vallabh prakashan.
3. "Biopharmaceutics and pharmacokinetics" by V. Venkatshwarlu pharma book syndicates
4. "Biopharmaceutics and pharmacokinetics" P.L. Madan, Jaypee publication.
5. A textbook of "Biopharmaceutics and pharmacokinetics" by Dr. Anant Paradkar and Sunil Bakaliwal, Nirali Prakashan.
6. Remington: The science and practice of pharmacy, 19th edition, vol. 1 and 2.
7. Gibaldi, M: "Biopharmaceutics and clinical pharmacokinetics. Lea and Febiger, Philadelphia.
8. Rowland, M, and Tozar, T.N. "Clinical pharmacokinetics, concepts and Applications." Lea and Febiger, Philadelphia.
9. Notari, R.E., "Biopharmaceutics and clinical pharmacokinetics", Marcel Dekker.
10. Gibaldi, M: and Perrier, D: "Pharmacokinetics", Marcel Dekker.
11. Leon shargel and Andrew B.C. Yu., "Applied Biopharmaceutics and pharmacokinetics" (Appleton century- Crofts)
12. Sarfaraz Niazi "Textbook of Biopharmaceutics and clinical pharmacokinetics" (Appleton century crofts, New York)

3.6 P.A -II

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Class: Third B. Pharm.

Subject: Pharmaceutical Analysis –II (Theory) **(3 lectures/ week)**

SECTION A

1. **An Introduction to Instrumental Methods. (1hr)**
   - Classification of Instrumental Techniques
   - Important considerations in Analytical methods
   - Basic Functions of Instrumentations

2. Basic concepts in speetroscopy: (3 hrs)

- Introduction: Electromagnetic Radiation, Wavelength, wave number, frequency, atomic spectra , molecular spectra, Measuring Photons as a Signal,Absorbance of Electromagnetic Radiation, Transmittance and Absorbance,

- Basic Components of Spectroscopic Instrumentation Sources of Energy, Wavelength Selection, Sample Cells, Detectors, Signal Processors

3. UV-visible absorption spectroscopy (8 hrs)

- Introduction, Origin and theory of UV spectra.
- Fundamental laws of Photometry.
- Instrumentation (Single and Double Beam)
- Bathochromic and Hypsochromic shift.
- Choice of solvents.
- Quantitative methodology.
- Differential or Expanded - Scale Spectroscopy
- Difference Spectroscopy.
- Derivative Spectroscopy.
- Photometric Titrations.
- Applications of UV-visible absorption spectroscopy in Pre formulation and formulation.
- Application to structural analysis

4. **Molecular Luminescence Spectrophotometry: (3hrs)**

- Introduction
- Theory of Fluorescence and Phosphorescence
- Factors Influencing Phosphorescence and Fluorescence
- Instrumentation
- Applications of Molecular Luminescence Spectrophotometry.

3.6 P.A II

5. Infrared Spectrophotometry: (6hrs)

- Introduction
- Range of IR radiations.
- Requirements of IR radiation: correct wavelength of radiation, Electric dipole.
- Theory of IR absorption spectroscopy.
- Modes of vibration of atoms in polyatomic molecules: Stretching vibrations, bending vibrations, types of stretching and bending vibrations.
- Interpretation of infrared spectra, quantitative analysis.
- Routine maintenance – Dispersive and FTIR instruments.
- Instrumentation, single beam, double beam spectrophotometer.
- Application to pharmaceuticals.
- Limitations of IR spectrophotometry.
- Structural Elucidation

6. Nuclear Magnetic Resonance Spectroscopy (9 hrs).

- The NMR Phenomenon
- Theory of NMR.
- Instrumentation.
- Chemical Shift and its Measurement.
- Factors Influencing Chemical Shift.
- Solvents used in NMR.
- Integrals in Proton NMR Spectra.
- Spin-Spin Coupling-Spin Spin Splitting.
- Factors Influencing the Coupling Constant *J*
- Applications of Proton NMR.
- C-13 NMR.
- Two- Dimensional Fourier Transform NMR.
- Magnetic Resonance Imaging.
- Structural Elucidation

7. Mass Spectrometry (8hrs)

- Basic Principle.
- Instrumentation
- Isotope abundances
- The Molecular Ion
- Metastable Ions
- Fragmentation Processes.
- Fragmentation associated with functional groups.
- Structural Elucidation

3.6 P.A -II

8. Problems on conjoint Structural Elucidation IR-UV/VIS-NMR-Mass Spectrometry (2hrs)

SECTION B

9. Introduction to solvent Extraction – (4 hrs)

- Principle of solvent extraction, distribution ratio, efficiency of extraction, Separation factor.
- Practical aspects of solvent extraction (Factors affecting liquid liquid extraction)
- Selection of solvent as an extraction solvent.
- Method of extraction: Batch extraction, countercurrent extraction, and continuous extraction.
- Stripping extraction and pH effect.
- Soxhlet extraction method.
- Salting out effect.

10. Atomic emission and atomic absorption spectrophotometry: (4 hrs)

- Principle.
- Differences between Atomic absorption spectroscopy and flame emission spectroscopy.
- Advantages of AAS over Flame emission Spectroscopy
- Limitation
- Instrumentation: single and double beam spectrophotometer.
- Pharmaceutical applications of Atomic emission spectroscopy, atomic absorption spectroscopy.

11. Introduction to Electroanalytical Methods of Analysis: (2 hrs)

- Electrochemical Cells
- Current Potential Relationship
- Mass transfer by Migration and Convection.
- Mass transfer by Diffusion.
- Types of Electroanalytical methods.

12. Potentiometry (4hrs)

- Theory
- Instrumentation
- Reference Electrodes
- The measurement of pH.
- Ion selective electrodes
- Ion activity evaluation methods

3.6 P.A -II

- Interferences
- Potentiometric Titrations.
- Applications.

13. Voltammetry (4 hrs)

- Introduction
- Excitation signals in Voltammetry
- Instrumentation
- Hydrodynamic Voltammetry
- Cyclic Voltammetry
- Stripping Methods
- Apllications.

14. Coulometry (2hrs)

- Introduction
- Potentiostatic Coulometry
- Coulometric Titrations
- Applications

15. Conductometry (2hrs)

- Introduction
- Electrolytic Conductivity
- Conductance Cells
- Conductivity meters
- Conductometric Titrations
- Applications

16. Polarography (3 hrs.)

- Diffusion Currents
- Half Wave Potentials
- Instrumentation
- DME
- Characteristics of DME
- Quantitative analysis
- Modes of operation used in Polarography
- Applications.

17. Thermal analysis: (6 hrs)

- Introduction to Thermal methods of analysis,
- Intoduction to Thermogravimetry (TG)
- Isothermal or static thermogravimetry , Quasistatic thermogravimetry.
- Recording of results, information from TG curves

- Factors affecting Thermogravimetric curves,
- Instrumentation for thermogravimetry ,
- Applications of TG .
- Differential thermal analysis (DTA) and Differential Scanning Calorimetry (DSC)
  - Classical DTA
  - Calorimetric DTA or Heat Flux DSC
  - Differential Scanning Calorimetry
  - Comparison of the Principles of DTA and DSC
  - Modulated Temperature DSC
  - Sample Containers and Sampling
  - Quantitative aspects of DTA and DSC Curves
  - Interpretation of DTA and DSC Curves
  - Determination of Phase Diagrams
  - General applications of DTA and DSC Curves

18. Radiochemical analysis (4 hrs)

- Nuclear reactions and radiations
- Measurement of radioactivity
- Neutron sources
- Activation analysis
- Isotope dilution analysis
- Liquid scintillation systems
- Applications of radio-nuclides

Recommended Books

1. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd Delhi/Madras. Instrumental methods of Analysis –Ewing (Marcel dekker)
2. Higuchi & Brochmann- Hanssen- Pharmaceutical Analysis - (Interscience)
3. Garratt - The quantitive analysis of Drugs (Toppan & co.)
4. Meites - HB of Analytical Chemistry (McGraw Hill).
5. Florey- Analytical profiles of Drugs substances (Academic press)
6. Gary Christian - Analytical Chemistry (John Wiley)
7. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
8. David G. Watson- Pharmaceutical Analysis (Elsevier)
9. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.David Harvey – Modern Analytical Chemistry (Mc Graw Hill)
10. F.W. Fifield- Principles and Practice of Analytical Chemistry (Blackwell Science)

3.6 P.A -II

11. Michael E Brown- Introduction to Thermal Analysis (Kluwer)
12. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
13. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
14. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
15. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
16. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
17. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
18. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
19. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
20. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
21. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
22. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
23. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
24. I.P.-1996, The Controller of Publications, New Delhi.
25. BPC- Dept. of Health, U.K. for HMSO.
26. USP - Mack Publishing Co., Easton, PA.
27. The Extra Pharmacopoeia – The Pharm. Press, London.

3.6 P.A II

Pharmaceutical Analysis-II

Practicals

3 hours / week / batch

A) Practicals:

1) Calibration of pH Meter
2) To determine the pka value of dibasic acid by using pH meter
3) To determine the pka value of tribasic acid by using pH meter.
4) To determine amount of HCL and phosphoric acid in a given mixture potentiometrically.
5) Calibration of conductometer and estimation of conductivity of distilled water.
6) Estimation of Boric acid by conductometric titration.
7) Calibration of UV- VIS spectrophotometer as per IP.
8) Effect of pH and solvent on the UV spectrum of given compound.
9) Determination of dissociation constant of indicators using UV-Visible spectroscopy.
10) Assay of following formulation / drugs using UV- VIS determination as per IP

Propanolol Tablets.

Paracetamol Tablets.

Atenolol tablets

Rifampicine / Rifampicine capsules

Albendazole tablets

11) Simultaneous spectrophotometry: determination of Fe^{+2} and Fe^{+3} by using 1,3 Phenathroline

12)Estimation of Salicylic acid by colorimetry

13) Assay by fluorimetry of a given drug: e.g quinine sulphate.

14) Study of quenching effect in fluorimetry.

15) Determination of k^{+} from kcl by flame photometry after preparing of calibration curve.

16) Experiment based on solvent extraction: Determination of percentage of chloroquine phoshate using solvent (ether) extraction

3.6 P.A -II

17) Colourimetric estimation of Supha drugs using BMR reagent

B) Demonstration Experiments:

- To prepare sample in kbr pellet, record its IR spectrum and compare it qualitatively with reported IR in IP / BP
- Comparison of the IR spectrum of a compound with that of its derivatives.
- Demonstration of DSC.
- Interpretation of NMR spectra of any one compound.

Books :

1. Practical Pharmaceutical chemistry - Part - I and II, Beckett and steanke Atholne Press.
2. Semi micro quantitative organic analysis - Cheronis and entrikin wiley interscience, pub.
2. Qualitative inorganic chemistry – A.I. Vogel, ELBS.
3. TLC by Stahl, Spring Verlay.

3.7 BIOTECH

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Subject: Biotechnology (Theory)
Third Year B.Pharm

Theory: 3hrs/week
Total: 75 Hrs

SECTION A

Definition and scope: Applications to different fields (1)

I] PLANT CELL AND TISSUE CULTURE (8) Best Ref.:1, 2, 3, 4

Structure of plant cell, DNA, Genes, and Chromosomes (1)

1. Cell and tissue culture (2)
   - i) Requirements
   - ii) Callus culture, Suspension culture, Batch culture
   - iii) Concept of Somatic Hybridisation, Somatic embryogenesis
3. PROCESSES AND APPLICATIONS
   - i) Isolation and immobilization of enzymes and plant cells and applications (1)
   - ii) Protoplast and cell fusion (1)
   - iii) Germplasm conservation (1)
   - iv) Production of secondary metabolites by plant tissue culture (1)
   - v) Gene transfer (biological and direct) (1)

II] ANIMAL CELL CULTURE (4) Best Ref.: 1,2, 3, 8

1. Genetic recombination in mammalian cells (1)
2. Mammalian genome, Human genome projects (1)
3. Transgenic animals as source of food, organs & tissues, concept of Xenotransplant (1)
4. Cloning: Concept and applications with technical hurdles (1)

III] FERMENTATION TECHNOLOGY AND INDUSTRIAL MICROBIOLOGY (10) Best Ref.:1, 2, 3, 4, 5

1. Fermentation as biochemical process, Types of fermentation (1)
2. Fermenter, Construction, accessory components, modifications and working (2)
3. fermentation monitoring and in-situ recovery of products (1)
4. Applications of fermentation
   - i. Manufacturing of antibiotics-Penicillin, Streptomycin, Tetracycline (2)
   - ii. Manufacturing of dextran and vitamins (1)
5. Waste discharge and effluent treatment. Concept of BOD, COD (1)
6. Microbial enzymes and their applications (1)

IV] IMMUNOLOGY AND HEALTH (3) Best Ref.: 2, 3

Concept of Immunization. Adjuvants and their role, Peptide vaccines, DNA vaccines Lymphokines and their role.

3.7 BIOTECH

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

Subject: Biotechnology (Theory)
Third Year B.Pharm

Theory: 3hrs/week
Total: 75 Hrs

SECTION A

Definition and scope: Applications to different fields (1hr.)

I] PLANT CELL AND TISSUE CULTURE (8 hr.) Best Ref.:1, 2, 3, 4

Structure of plant cell, DNA, Genes, and Chromosomes (1 hr.)

1. Cell and tissue culture (2 hr.)
   - i) Requirements
   - ii) Callus culture, Suspension culture, Batch culture
   - iii) Concept of Somatic Hybridisation, Somatic embryogenesis
3. PROCESSES AND APPLICATIONS
   - i) Isolation and immobilization of enzymes and plant cells and applications (1 hr.)
   - ii) Protoplast and cell fusion (1 hr.)
   - iii) Germplasm conservation (1 hr.)
   - iv) Production of secondary metabolites by plant tissue culture (1 hr.)
   - v) Gene transfer (biological and direct) (1)

II] ANIMAL CELL CULTURE (4 hr.) Best Ref.: 1,2, 3, 8

1. Genetic recombination in mammalian cells (1 hr.)
2. Mammalian genome, Human genome projects (1 hr.)
3. Transgenic animals as source of food, organs & tissues, concept of Xenotransplant (1 hr.)
4. Cloning: Concept and applications with technical hurdles (1)

III] FERMENTATION TECHNOLOGY AND INDUSTRIAL MICROBIOLOGY (10 hr.)

Best Ref.:1, 2, 3, 4, 5

1. Fermentation as biochemical process, Types of fermentation (1 hr.)
2. Fermenter, Construction, accessory components, modifications and working (2 hr.)
3. fermentation monitoring and in-situ recovery of products (1 hr.)
4. Applications of fermentation
   - i. Manufacturing of antibiotics-Penicillin, Streptomycin, Tetracycline (2 hr.)
   - ii. Manufacturing of dextran and vitamins (1 hr.)
5. Waste discharge and effluent treatment, Concept of BOD, COD (1 hr.)
6. Microbial enzymes and their applications (1 hr.)

3.7 BIOTECH

IV] IMMUNOLOGY AND HEALTH (3 hr.) Best Ref.: 2, 3

Concept of Immunization, Adjuvants and their role, Peptide vaccines, DNA vaccines Lymphokines and their role,

V] RECOMBINANT DNA TECHNLOGY (12 hr.) Best Ref.: 1,2, 3, 5, 6,7

1. BASIC CONCEPTS: (2 hr.)
   - i Introduction
   - ii Structure of Genes and genome and nucleic acid
   - iii Nucleic acid purification
   - iv Role of Restriction endonuclease, DNA ligase, DNA polymerase, Reverse transcriptase

   Note: Time allotted for point i and ii 1 hr & Point iii and iv 1 hr
2. PROCESS AND APPLICATIONS (10 hr.)
   a) Constructing Recombinant DNA molecules (5 hr.)
      i. DNA clones- sources of DNA for cloning (1 hr.)
      ii. Cutting and joining DNA, Restriction endonucleases their type and role (1 hr.)
      iii. DNA vectors, Role of expression vectors (1 hr.)
      iv. Host cell for Recombinant work
      v. Method for screening and selecting transformants
      vi. Expression of foreign genes
      vii. Uses of recombinant DNA

      Note: Point iv and v should be completed within 1 hr & Point vi and vii should be completed within 1 hr

   b) PCR and applications (1 hr.)
   c) Site directed mutagenesis (1 hr.)
   d) Human gene therapy concept and applications, Concept of stem cells (1 hr.)
   e) Drug delivery systems in Gene therapy (1 hr.)
   f) DNA fingerprinting, RFLP (1 hr.)

SECTION B

VI] BIOTECHNOLOGY DERIVED PRODUCTS (18 hr.) Best Ref.:7

A) Sources and upstream processing (5 hr.) Best Ref.:7

1. Introduction
2. *Escherichia coli* as a source of recombinant, therapeutic proteins (1 hr.)
3. Expression of recombinant proteins in animal cell culture systems (1 hr.)
4. Additional production systems (2 hr.)
   - i Yeast
   - ii Fungal production systems
   - iii Transgenic animals
   - iv Transgenic plants
   - v Insect cell-based systems
5. Upstream processing (1 hr.)
   - ❖ Cell banking systems

- ❖ Microbial cell fermentation
- ❖ Mammalian cell culture systems

Note: (Time allotted for point ii and iii is 1 hour)

B) Downstream processing (5 hr.) Best Ref.:7

1. Introduction
2. Initial product recovery
3. Cell disruption
4. Removal of nucleic acid
5. Initial product concentration
6. Ultrafiltration
7. Diafiltration
8. Chromatographic purification (2 hr.)
    a. Size-exclusion chromatography (gel filtration)
    b. Ion-exchange chromatography
    c. Hydrophobic interaction chromatography
    d. Affinity chromatography
    e. Immunoaffinity purifi cations
    f. Protein A chromatography
    g. Lectin affinity chromatography
    h. Dye affinity chromatography
    i. Metal chelate affinity chromatography
    j. Chromatography on hydroxyapatite
    k. Chromatofocusing
    l. High-performance liquid chromatography of proteins
9. Purification of recombinant proteins
10. Final product formulation
11. Proteolytic degradation and alteration of sugar side-chains
12. Protein deamidation
13. Oxidation and disulfide exchange
14. Stabilizing excipients used in fi nal product formulations
15. Final product fill
16. Freeze-drying
17. Labelling and packing

Note: (Time allotted for point 1-7 is 1 hour)
(Time allotted for point 9-13 is 1 hour)
(Time allotted for point 14-17 is 1 hour)

C) Product analysis (6 hr.) Best Ref.:7

1. Introduction
2. Protein-based contaminants
3. Removal of altered forms of the protein of interest from the product stream
    a. Product potency
    b. Determination of protein concentration
4. Detection of protein-based product impurities by, (1 hr.)
    a. Capillary electrophoresis
    b. High-performance liquid chromatography

c. Mass spectrometry

5. Immunological approaches to detection of contaminants (2 hr.)
   a. Amino acid analysis
   b. Peptide mapping
   c. N-terminal sequencing
   d. Analysis of secondary and tertiary structure
6. Endotoxin and other pyrogenic contaminants (2 hr.)
   a. Pyrogen detection
   b. DNA as contaminant
   c. Microbial and viral contaminants
   d. Viral assays
   e. Miscellaneous contaminants
   f. Validation studies

Note: (Time allotted for point 1-3 is1 hour)

D) Production and Purification of Biotechnology Recombinant Proteins like, (2 hr.)

- ❖ Insulin, Growth hormone, Somatostatin, Interferons,
- ❖ Only examples of Recombinant blood product

VII] PROTEOMICS (12 hr.) Best Ref.:6

1. Introduction
2. What is a Proteome
3. Technologies for Proteomics
4. Protein Identification,
   - o 1-D-SDS-PAGE (1-dimensional sodium dodecyl sulfate-polyacrylamide gel electrophoresis)
   - o 2-Dimesional Electrophoresis (2 hr.)
     - i Steps of 2-DE
     - ii Resolution of 2-DE Gels
     - iii Reproducibility of Protein Profiles Obtained by -DE
     - iv Stains and Dyes of 2-DE
     - v Image Analysis in 2-DE
     - vi Drawbacks of -DE/SDS-PAGE
6. Role of, (1 hr.)
   - i Isoelectric Focusing (IEF)
   - ii High Performance Liquid Chromatography
   - iii Capillary Electrophoresis in proteomics
7. Protein Digestion
8. Mass Spectrometry (MS) for Proteomics
   - i MALDI-TOFF (Matrix assisted Laser Desorption Ionization -Time of Flight
   - ii ESI (Electrospray Ionisation) and Tandem MS
9. Techniques Used for Structural Proteomics (2 hr.)
   - i. X-Ray Crystallography and Drawbacks of X-Ray Crystallography
   - ii. Nuclear Magnetic Resonance
   - iii. Phage Display Technique for Functional Proteomics
   - iv. Fields of Application for Phage Display Technique

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10. Bioinformatics (1 hr.)
11. DNA and Protein Microarray Technologies (2 hr.)
    i. DNA Arrays
    ii. Design of a Microarray System
    iii. Attachment of a Single DNA Molecule to a Silicon Surface How to Choose an Array
12. Protein Arrays (1 hr.)
13. Applications of DNA and Protein Microarray Technology (1 hr.)
14. Pharmaceutical and Medical Applications of Proteomics (1 hr.)

(Note: Points 1-4 should be completed within 1 hr)
(Time allotted for point 7 and 8 is 2 hr)

VIII] FORMULATION OF PROTEINS AND PEPTIDES (8 hr.) Best Ref.:6

1. Introduction
2. Making Small Protein Particles: Precipitation of Proteins from Supercritical Fluids
3. Parenteral Drug Delivery Systems
   General Introduction
   Bacterial Death , Sterilization Methods, Heat Sterilization, Moist Heat Dry Heat. Sterilizing Gases, Ionizing Radiation, Sterile Filtration, The Concept of "Size" as Related to a Filtration
4. Aseptic Assembly
5. Quality Control Issues
6. Lyophilization (Freeze-Drying)
7. Drug Delivery through the Skin and Iontophoresis
8. Multiphase Drug Delivery Systems
   Microemulsions (1 hr.)
   - ❖ Microemulsions as Particulate Systems
   - ❖ Spontaneous Microemulsion Formation
10. Protein Compaction (1 hr.)
11. Self-Emulsifying Drug Delivery Systems (1 hr.)
    - ❖ Evaluation of SEDDS Performance Parameters
    - ❖ Selection of Components for a SEDDS
    - ❖ Possible Mechanisms for the Formation of Self-Emulsified Emulsions

Note: Time allotted for point 1-4 is 1 hour
Time allotted for point 4-7 is 2 hour

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