NORTH MAHARASHTRA UNIVERSITY, JALGAON

STRUCTURE AND SYLLABUS

M. PHARM. COURSE STRUCTURE

SPECIALIZATION: PHARMACOLOGY

(w.e.f. Academic year 2004 –05)

ANNEXURE - I D

Semester	No. and Title of Paper	Scheme of Teaching Hours/week		Scheme of Examination				Total
				Theory		Practical		
		Lectures	Practicals	Hrs.	Marks	Hrs.	Marks	
I	Adv. Pharmacology - I	03	06	03	100	08	100	200
	Advanced Analytical Techniques	03	06	03	100	08	100	200
	Elective-I	03	-	30	100	-	-	100
	Seminar (on Topic of Specialization subject)	01 per student		A/B/C/D		-	-	-
	Research Work	-	15	-	-	-	-	-
II	Adv. Pharmacology-II	03	06	03	100	08	100	200
	Elective- II*	03	-	03	100	-	-	100
	Elective – III	03	-	03	100	-	-	100
	Seminar (on Topic of Specialization subject)	01 per student		A/B/C/D		-	-	-
	Research Work	-	20	-	-	-	-	-
III	Seminar (on Research work done)	01 per student		A/B/C/D		-	-	-
	Research Work	-	35	-	-	-	-	-
IV	Seminar (on Dissertation)	01 per students		A/B/C/D		-	-	-
	Dissertation and Viva-voce	-	35	-	-	-	-	300
	GRAND TOTAL							1200

NOTE: (1) A/B/C/D indicates the grade secured by the student in the Seminar (2) Theory and Practical are separate heads

* Elective II should be related to Branch of specialization (3) Distribution of Marks for dissertation and Viva-Voce shall be as under:

Dissertation Work		Viva - Voce	
(a) Reference work	= 30	(a) Scientific contents	= 20
(b) Experimental Work	= 60	(b) Presentation / Communications	= 20
(c) Scientific Contents	= 20	(c) Discussion	= 20
(d) Presentation/ Communication	= 40	(d) Report	= 40
(e) Result/ Conclusion	= 50		
Total Marks = 200		Total	=100

Advanced Pharmacology-I

(Advances in Preclinical Evaluation)

(Theory) 3 Hrs per week (40 hrs)

1. **Care, handling and breeding techniques** of laboratory animals. Regulations for laboratory animal care and ethical requirement. Knowledge of the CPCSEA proforma for performing experiments on animals. Alternatives to animal studies. **(06hrs)**
2. **Organization of preclinical screening** programme (Blind screening) **(03hrs)**
3. **Preclinical evaluation** of following categories of drugs. **(19hrs)**

   i. Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, noortropics, antiparkinsonian agents, analgesics, antipyretics:
   ii. Anti-inflammatory agents, anticonvulsants, local anesthetics, CNS stimulations
   iii. Cardiac glycosides, antiarrhythmic, antithypertensives, antitatherosclerotics,
   iv. Antiulcer agents, laxatives, bronchodilators, antitussives,
   v. Diuretics.
   vi. Histamine antagonists.
   vii. Muscle relaxants, anticholinesterages, anticholinergics, adrenolytics.
   viii. Hypoglycemics, antifertility agents, andrognes.
   ix. Anti-thyroid agents, Dermatological agents, Antitumor agents.

4. **Concept of transgenic animals**, knockout animals, nude animals, receptor binding assays, principles of immunoassay, patch clamp techniques. **(06hrs)**
5. **In vitro testing of drugs**. Animal cell lines and their uses. Limitation of in vitro testing of drugs. **(06hrs)**

rence Books:

Evans CL, Principles of Human Physiology, J and A Churchill Ltd. London

Guyton LC, Text Book pf Medical Physiology, Saunders Co., London

Best CH and Taylor NB, The Physiological Basis of Medical Practice, The Williams and Wilkins Co., Baltimore

Jensen D, The Principles of Physiology, Appletton-Century-Crofts, New York

Vander A, Sherman JH and Luciano D. Human Physiology – The Mechanisms of Body Functions, Tata McGraw Hill Publishing Co., New Delhi.

Goodman and Gilman: Pharmacological Basis of Therapeutics, Pregamon Press, New York.

Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation.

Turner RA, Screening Methods in Pharmacology, Academic Press, London

Goldsteine, Principles of Drug Action, John Wiley and Sons, New York

0. Crossland J, Lewis's Pharmacology, Churchill Livingstone, Edinburgh

1. Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
2. Bacq ZM, Capek, Fundamentals of Biochemical Pharmacology
3. Laurence = DR, = Bennett = PN, = Borown = MJ, = Clinical Pharmacology, Churchill Livingstone, New York
4. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
5. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
6. Review articles from published journals.

ADVANCED PHARMACOLOGY – I
(Advances in Preclinical Evaluation)
(Practical) 6 Hrs/week (60 hrs)

1. Preparation of vaginal smears and examination un microscope.
2. Methods of handling experimental animal.
3. Standard techniques for injection of drugs, collection of blo samples and feeding of animals.
4. Use of anesthetics and cannulation of veins, arteries a trachea. Working of psychographs (student and biopac) setti rat/ rabbit B. P., ECG recording.
5. Neuropharmacological screening test
6. Experiments based on screening methods of various categor of drugs.
    - CNS stimulant and CNS depressants
    - Anticonvulsants
    - Antidepressants
    - Antifertility
    - Catalepsy
    - Antipsychotics
    - Anxiolytics
    - Analgesics and anti-inflammatory
    - Mydriatric and mitotic

Reference Books:

1. Lawrence DR and Bacharach AL, Evaluation of Dr Activities: Pharmacometrics, Academy Press, London.
2. Goodman and Gilman: Pharmacological Basis of Therapeuti Pregamon Press, New York.
3. Nodine Siegler, Animal and Clinical Pharmacologi Techniques in Drug Evaluation.
4. Turner RA, Screening Methods in Pharmacology, Acaden Press, London

5. Goldsteine, Principles of Drug Action, John Wiley and Sons, New York
6. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
7. Review articles from published journals.

ADVANCED PHARMACOLOGY – II
(Applied Pharmacology and Regulatory toxicology)
(Theory) 3 Hrs/week (40 hrs)

1. **Safety Pharmacology / regulatory toxicology:** **(20 hrs)**
   a. Preparation of protocol for safety assessment
   b. OECD guidelines for toxicity testing
   c. Toxicity testing by acute, sub-acute, chronic toxicity including local toxicity, allergencity.
   d. Genomes toxicity, dermatotoxicity, reproductive genocity, terratogenicity, carcinogenicity, phototoxicity
   e. Knowledge of documentation and protocol preparation, knowledge of planning, performing, analyzing, reporting and monitoring of above toxicity.
2. **Clinical Trials**: Clinical evaluation of new drug, phases of clinical trail, ethics and protocol. Preparation of clinical trail. New drug development process and drugs registration. **(10hrs)**
3. **Introduction to molecular biology (Bioinformatics) / Computational Biology** Basics of DNA, RNA and protein, Structure of cell, cell reproduction, concept of gene, control of protein synthesis. Introduction to Southern Blots, Northern Blots, Western Blots, Cloning and Sub-cloning. **(10hrs)**

Reference Books:

1. Evans CL, Principles of Human Physiology, J and A Churchill Ltd. London
2. Guyton LC, Text Book pf Medical Physiology, Saunders Co., London

3. Best CH and Taylor NB, The Physiological Basis of Med Practice, The Williams and Wilkins Co., Baltimore
4. Jensen D, The Principles of Physiology, Appletton-Centu Crofts, New York
5. Vander A, Sherman JH and Luciano D. Human Physiolog The Mechanisms of Body Functions, Tata McGraw Publishing Co., New Delhi.
6. Goodman and Gilman: Pharmacological Basis of Therapeut Pregamon Press, New York.
7. Nodine Siegler, Animal and Clinical Pharmacolog Techniques in Drug Evaluation.
8. Turner RA, Screening Methods in Pharmacology, Acade Press, London
9. Goldsteine, Principles of Drug Action, John Wiley and So New York
10. Crossland J, Lewis's Pharmacology, Churchill Livingsto Edinburgh
11. Katzung BG, Basic and Clinical Pharmacology, Lange Medi Publication, California
12. Bacq ZM, Capek, Fundamentals of Biochemi Pharmacology
13. Laurence DR, Bennett PN, Borown MJ, Clini Pharmacology, Churchill Livingstone, New York
14. Vogel HG, Drug Discovery and Evaluation, Springer, Germa
15. Lawrence DR and Bacharach AL, Evaluation of Dr Activities: Pharmacometrics, Academy Press, London.
16. Rothstein, MA, Pharmacogenomics, Wiley-Liss, New Jersey
17. Lesk, AM, Introduction to Bioinformatics, Oxford Univers Press, Oxford.
18. Khan, IA and Khanum, A, Recent Advances in Bioinformati Ukaaz Publications, Hyderabad.
19. Review articles from published journals.

ADVANCED PHARMACOLOGY – II
(Applied Pharmacology and Regulatory toxicology)
(Practical) 6 Hrs/week (60 hrs)

1. Demonstration of the pharmacological effects of autonomic drugs using rats B.P.and other parameters.
2. Calculations of pA2 and pD2 values using isolated tissue preparations: Suitable isolated animal tissue.
3. Bioassay of autonomic drugs: Acetylcholine
4. Bioassay of autocoids: Histamine, oxytocin
5. Use of HPLC, Spectrofluormeter in estimation of drugs
6. LD_{50} determination as per OECD guideline
7. LAL test

Reference Books:

1. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
2. Goodman and Gilman: Pharmacological Basis of Therapeutics, Pregamon Press, New York.
3. Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation
4. Turner RA, Screening Methods in Pharmacology, Academic Press, London
5. Goldsteine, Principles of Drug Action, John Wiley and Sons, New York
6. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
8. Perry WLM: Pharmacological Experiments on Isolated Preparations, E & S Livingstone, London
9. Ghosh MN, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta
7. Kulkarni SK, Handbook of Experimental Pharmacology, Vallabh Prakashan, Delhi

8. Seth UK, Dadkar NK, and Kamat UG: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Bombay
9. Review artciles from published journals.

Elective

Advances in Novel Pharmacological Drugs Target

1. Molecular mechanisms of drug action: Receptor occupancy and cellular signaling system such as G-proteins, cyclic nucleotides, calcium and phosphatidylinositol. Ionic channels and their modulators.
2. Endogenous bioactive molecules as TNF Interleukins, Process of apoptosis, arachidonic acid metabolites, COX-2 regulators and their role in inflammation.
3. Recent trends on different classes of receptors and drugs acting on them
    a. Cholinergic receptors
    b. Dopamine receptors
    c. Serotonin receptors
    d. Hormone receptors
    e. GABA receptors
    f. Opioid receptors
    g. Purinergic receptors
    h. Glutamate receptors
4. Neurosteroids, Nitric oxide.
5. Endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.
6. Fc-receptors on T and B lymphocytes, Antibody dependent and cellular cytotoxicity.
7. Concept of gene therapy and recent development in the treatment of various hereditary diseases. Human genome mapping and its potential in drug research.
8. Antisence genes as a research tool.

ooks Recommended:

1. Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
2. Barar F.S.K Essentials of pharmacotherapeutics (S.Chand & C. New Delhi)
3. Bow man W. C. and Rand M. J. Text book of Pharmacology (Blackwell, Oxford)
4. Melmon K. L. and Morelli. Clinical pharmacology Basic principles of Therapeutics (Macmillan New York)
5. Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston)
6. Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
7. Grollman Pharmacology & Therapeutics (Lea and Tebiger Philadelphia)
8. Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology.
9. Avery G. S. Drug treatment (Adis Press, Sydney)
10. Goodman and Gilman Pharmacological Basis of Therapeutics (MacGraw Hill)
11. Rang H. P. and Dale M. M. Pharmacology (Churchill Livingston, U. K.)

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STRUCTURE AND SYLLABUS
M. PHARM. COURSE STRUCTURE
SPECIALIZATION: PHARMACEUTICS
(w.e.f. Academic year 2004–05)

ANNEXURE - I E

Semester	No. and Title of Paper	Scheme of Teaching Hours/week		Scheme of Examination				Total
				Theory		Practical		
		Lectures	Practicals	Hrs.	Marks	Hrs.	Marks	
I	Adv. Pharmaceutics - I	03	06	03	100	08	100	200
	Advanced Analytical Techniques	03	06	03	100	08	100	200
	Elective-I	03	-	30	100	-	-	100
	Seminar (on Topic of Specialization subject)	01 per student		A/B/C/D		-	-	-
	Research Work	-	15	-	-	-	-	-
II	Adv. Pharmaceutics-II	03	06	03	100	08	100	200
	Elective- II*	03	-	03	100	-	-	100
	Elective – III	03	-	03	100	-	-	100
	Seminar (on Topic of Specialization subject)	01 per student		A/B/C/D		-	-	-
	Research Work	-	20	-	-	-	-	-
III	Seminar (on Research work done)	01 per student		A/B/C/D		-	-	-
	Research Work	-	35	-	-	-	-	-
IV	Seminar (on Dissertation)	01 per students		A/B/C/D		-	-	-
	Dissertation and Viva-voce	-	35	-	-	-	-	300
	GRAND TOTAL							1200

NOTE: (1) A/B/C/D indicates the grade secured by the student in the Seminar (2) Theory and Practical are separate heads

* Elective II should be related to Branch of specialization (3) Distribution of Marks for dissertation and Viva-Voce shall be as under:

Dissertation Work

(a) Reference work	= 30
(b) Experimental Work	= 60
(c) Scientific Contents	= 20
(d) Presentation/ Communication	= 40

Viva - Voce

(a) Scientific contents	= 20
(b) Presentation / Communications	= 20
(c) Discussion	= 20
(d) Report	= 40

(01)

ADVANCED PHARMACEUTICS-I (THEORY)

Theory (3hrs/week) (40 hrs)

ysical Pharmaceutics:

1. **Preformulation:** Techniques for physico-chemical characterization of drug and excipient significance and methods for evaluation of drug-excipient, excipient- excipient and drug-container interactions and incompatibilities. **(06hrs)**
2. **Solid:** Recent techniques for particle size enlargement and micronization, compatibility and compressibility, different methods of evaluation of lubricant efficiency. **(04 hrs)**
3. **Biopharmaceutical evaluation of D.D.S.:** Theories of drug dissolution, dissolution test apparatus, selection of dissolution medium, dissolution of different dosage form solids, suspensions, topical, suppositories and controlled release systems. Enhancement of dissolution rate. Biopharmaceutical classification system, In-vivo dissolution techniques, in vitro models for evaluation and cell culture techniques. **(06 hrs)**
4. **Surfactant System:** Phase behavior of surfactant in binary and ternary systems. Factors affecting phase behavior. Micellization micelle structure, shape, size factor affecting CMC and micellar size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of solublization, solubization in non-aqueous systems, interaction with polymers and oppositely charged species. Hydrotropy in pharmaceuticals, surfactants in emulsions and suspension. Effect on dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity. Cyclodextrin inclusion complexes and co-solvents. **(12 hrs)**
5. **Biostatistics:** Different distributions, fiducial limits, linear regression and correlation, and their significance, parametric tests, type of error, hypothesis testing, non parametric tests, experimental designs, statistics in bioequivalence testing , statistical quality control, in-vitro in-vivo correlation. **(12 hrs)**

ADVANCED PHARMACEUTICS – I (PRACTICAL)

Theory (6 hrs/week) (60 hrs)

1. Drug – Excipient Interaction: HPLC, IR, UV, TLC.
2. Heckel plot analysis and lubricant sensitivity.
3. Comparative evaluation of Intrinsic dissolution rate of dr crystallized from different solvents.
4. Preparation and characterization of solid dispersions.
5. Dissolution testing of different types of dosage for (minimum 5)
6. Urinary excretion studies of sulphamethoxazole.
7. Drug absorption study by everted rate intestine technique.
8. Ternary phase diagram of surfactant system.

Books Recommended:

1. Remington's Pharmaceutical Sciences: Arthur Osal (Editor Mack Publishing Company Easton, Pennsylvanin 10842.
2. Theory and practice of Industrial Pharmacy Leon Lachma Herbert A. Lichman and Joseph L. Kanin. Varghese Publishir House, Bombay.
3. Essential of Physical Chemistry and pharmacy Arnikar, Kadam, Gujar, Orient Longman.
19. Quality Control in The pharmaceutical Industry: Volumes 1 and 3, Murrary S. Copper Academic Press, New York ar academic Press London.
20. Good Manufacturing Practices for pharmaceuticals – A pl for total Quality Control.
21. S. H. Willing, M. M. Tuckermanm S. Hilchings, Marc Dekker, Inc. New York.
22. Pharmaceutical Preformulation by J. 1. Wells, John wiley sons, N.Y.
23. Chemical Stability of Pharmaceutics – A Handbook fo Pharmacists – Kenneth A Connors, Gordon L. Amidon Voluation J. Stelle, John Wiley & Sons, New York.

Pharmaceutical Dosage Forms: Parenteral Medications Volumes 1, 2 and 3. Kenneth E. Vavis, Loan Lachman and Herbert A. Lichman. Marcel Dekker New York.
0.Pharmaceutical Dosage Froms: Diperse System Vol. 1 & 2 Edited by as 13.
1.Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.
2.Sterile Dosage Forms, Salvatore Turbo and Rebest E. King Lea and Febiger, Philadelphia.
3.Pharmaceutics – The Sciences of Dosage Form Design Michael E. Aulton, Churchill Livingstone, New York.
4.Advances in Pharmaceutical Sciences, Edited by Bean, Bockett and Carless, Academic Press, New York.
5.Dermatological Formulation – Percutaneout Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
6.Physical Pharmacy: A. N. Martine, James Swerbrick and Commarate (Lea & Febiger, Philadelphia)

ADVANCED PHARMACEUTICS-II (THEORY)

(3hrs/week) (40 hrs)

Basic considerations of novel drug delivery systems: (02hrs) Biopharmaceutical aspects and technology transfer of CDDS.

Oral drug delivery systems: Based on different control mechanism such as Osmotic pressure, membrane controlled pH, ion-exchange, gastrointestinal transit, pulsatile, colon specific etc. **(09 hrs)**

Mucosal drug delivery: Physiological, biopharmaceutical consideration, formation and models used. **(02hrs)**

Buccal: Physiology and permeability of oral mucosa, penetration enhancement, drug delivery systems and in-vitro and in-vivo techniques. **(04 hrs)**

Nasal: Anatomy and physiology of nasal mucosa, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation. **(04 hrs)**

C) Pulmonary: Structure and function of pulmonary system, facto affecting deposition in lungs. Dosage forms: Nebulize pressurized inhalation aerosols, aerosol powder. **(04 hr**

D) Rectal: Physiology, advantages, dosage forms and evaluati models. **(03 hr**

4) **Intrauterine and intravaginal drug delivery.** **(03 hr**
5) **Ocular drug delivery:** Mechanism and development of ocular dr delivery. **(03 hr**
6) **Transdermal drug delivery:** Percutaneans absorption, invitro a in-vivo evaluation. **(03 hr**
7) **Microencapsulation:** Applications, various techniques, facto affecting on stability manufacturing equipment.
8) **Cosmoceuticals and neutraceuticals:** Application and introducti to various techniques. **(03 hr**

Recommended Books:

1) P. Tyle; Drug Delivery Devices, fundamental and applicatio Marcel Dekker.
2) Morton Rosoff; Controlled release of drugs; VCH Publishers.
3) Osborne, and Amann; Topical drug delivery formulations; Mar Dekker.
4) P. Tyle; Drug delivery devices: Marcel Dekker.
5) Barry: Dermatological formulation; Marcel Dekker
6) Robinson; Novel Drug Delivery systems; Marcel Dekker
7) N.K. Jain; controlled and novel drug delivery; CBS Publicati New Delhi
8) P. Johnson and J. G. Lloyd – Jones; Drug delivery systems; V Publisher
9) P. Tyle and B. P. Ram; Targeted therapeutics systems; Mar Dekker.
10) C.G. Wilson & N. Washington; Physiological Pharmaceutics; E Horwood Limited.
11) H.S. Bean, A.H. Beckett, and J.E. Carless; Advances Pharmaceutical Sciences; Vol. 5, Academic Press.

R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivry; Marcel Dekker
T.J. Roseman and S.Z. Mansdorf; Contolled release delivery systems; Marcel Dekker
A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology; Marcel Dekker.
J. Kreuter; Controlled drug delivery system; Marcel Dekker
P.B. Deasy; Microencapsulation and related drug processes; Marcel Dekker.

ADVANCED PHARMACEUTICS-II (PRACTICAL)
(6hrs/week) (60 hrs)

1) Formulation of sustained release tablet formulation.
2) Formulation of gastro retentive drug formulation.
3) Formulation of colon specific drugs formulation.
4) Preparation and evaluation of microcapsules / Microspheres.
5) Preparation and evaluation of transdermal patches.
6) In-vitro permeation studies across skin and nasal mucosa.
7) Bioavailability study of a oral drug formulation.
8) Formulation and evaluation of a) Liposome b) multiple emulsion.

ELECTIVE

Novel Drug Delivery System (40 hrs)

Molecular basis of targeted drug delivery. **(12 hrs)**
General consideration, methods of preparation, characterization and applications of Lipsomes, niosomes, resealed erythrocytes, nanoparticulate systems, solid lipid nano-particles (SLN), dentrimers, multiple emulsions and nanoemulsions , organogels . **(18 hrs)**
Overview and applications of Aquasome, pharmacosomes, transferosomes, liquid crystalline systems, protein and peptide drug delivery system. **(10 hrs)**

Books Recommended

1. Jain N. K. "Controlled and novel drug delivery; CB Publication, New Delhi"
2. Jain N. K. Advances in controlled and Novel Drug Deliver CBS Publications and distributors, New Delhi.
3. Vyas S. P. and Khar R. K. "Controlled Drug Delivery-conce and Advances" Vallabh Prakashan, New Delhi.
4. Vyas S. P. and Khar R. K. "Targeted and controlled Dru Delivery – Novel Carrier system" CBS Publications, Ne Delhi
5. Chien Y. "Novel Drug Delivery System" Marcel Dekk Publication.

Elective
Packaging Technology (40 hrs)

1.	Concept in Pharmaceutical packaging	(03 hr
2.	The packaging function	(02 hr
3.	Regulatory aspects of pharmaceutical packaging system	(02 hr
4.	Package design research	(03 hr
5.	Packaging materials with special reference of glass, plastics, metals and polymers.	(05 hr
6.	Control of packaging materials.	(03 hr
7.	Ancillary materials used in packaging.	(01 hr
8.	Types and testing of containers and closures Pharmacopoeial tes and specifications closure system.	(03 hr
9.	Types of packaging with special reference to blister, strip, sache child resistant and tamper evident packaging.	(05 hr
10.	Packaging of parentral, ophthalmic and aerosols.	(03 hr
11.	Stability of packages and packaging materials	(03 hr
12.	Sterilization of packaging materials	(02 hr
13.	Printing and decoration of labels and packages	(01 hr
14.	Package testing	(03 hr
15.	Defects in packaging.	(01 hr

ooks Recommended

1. Swarbric, J and Bolyln, J. C., Encyclopedia of Pharmaceutical Technology Vol. 1-3, Marcel Dekker, Inc., New York.
2. Dean, D. A. Evans, E. R. and Hall, j. H. "Pharmaceutical Packaging Technology", Taylor and Francis, London.
3. Banker, G. S. and Rodes, C. "Modern Pharmaceutics", Marcel Dekker, Inc. N. Y.
4. Aulton, M.E., Pharmaceutics – The Science of dosage form design, Churchill Livgstone, U.K.
5. Lachman, L. Lieberman, H.A. and Kanig, J. L. Varghese Publishing House, Bombay
6. Gennaro, A. R. "Remington – The science and practice of Pharmacy" Lippincott Williams and Wilkins, Philadelphia

Elective (40 hrs)

DRA, Intellectual property right and Quality Assurance

1. Requirement of GMP, cGMP, GLP, USFDA, WHO guidelines and ISO 9000/14000 series. **(05 hrs)**
2. Drug and cosmetics Acts and Rules, Drug Regulatory Affairs. **(02 hrs)**
3. Documentation: Protocols, forms and maintenance of records in pharmaceutical industry. **(03 hrs)**
4. Preparation of documents for new drug approval and export registration. **(02 hrs)**
5. Patent processing and its application, Intellectual property rights (Patent, Copyright and trade marks) **(04 hrs)**
6. Sewage disposal and pollution control **(02 hrs)**
7. Concepts in validation, validation of manufacturing, analytical process validation and its applications. **(03 hrs)**
8. Basic concepts of quality control and quality assurance ystems, source and control of quality, variation of raw materials: Containers, closures, personnel, environmental etc. **(05 hrs)**
9. In process quality control tests, IPQC problems in pharmac euticals industries, ICH guidelines. **(05 hrs)**

10. Sampling plans, sampling and characteristic curves. **(04 hrs)**
11. Master formula generation and maintenance, standard operating procedure (SOP) for different dosage forms. **(05hrs)**

Books Recommended:

1. Willing, S. H. "Good Manufacturing Practices for Pharmaceuticals" Marcel Dekker, Inc. New York
2. Drugs and Cosmetics Acts and Rules.
3. Bharathi, Drugs and Pharmacy Laws in India.
4. Patel, A. H. "Industrial Microbiology" Macmillan India Ltd., Delhi
5. Nash R. A. and Wachter, A. H. "Pharmaceutical Process Validation" Marcel Dekker, Inc, New York.
6. Bolton, S. Pharmaceutical statistics.
7. Banker, G. S. and Rhodes, C. T. "Modern Pharmaceutics", Marcel Dekker, ince, New York
8. OPPI, Quality Assurance
9. Carleton, F. J. And Agallow, J. P. "Validation of Aseptic Pharmaceutical Processes" Marcel Dekker, Inc., New York
10. Garfield, Quality Assurance Principles of Analytical Laboratories
11. Indian Pharmacopoeia, The controller of Publications, Govt. of. India, Delhi.

Elective

Biotechnology and Bioinformatics (40 hrs)

Genetics: Structure and function of DNA, DNA replication and repair. Expression of genetic information, structure and function of RNA transcription, genetic code, translation, post translational modification. **(06 hrs)**

Recombinant DNA technology: Constructing recombinant DNA molecules, restriction enzymes, vectors, Gene cloning, genomic libraries, polymerase chain reaction based DNA cloning, restriction mapping, blotting techniques, DNA sequencing, pharmaceutical applications of recombinant DNA. **(08 hrs)**

Gene Therapy: Potential target diseases of gene therapy , gene transfer methods, clinical studies, pharmaceutical production and resolution. **(04 hrs)**

Basic immunology: Monoclonal antibodies and hybridoma technology and its applications, vaccine technology. **(05 hrs)**

Fundamentals of cell biology: Cell organization and plasma membrane, cellular reproduction and cell signaling. **(04 hrs)**

Molecular biology of cancer: Genetics of cancer new strategies for combating cancer. **(04 hrs)**

Molecular structure and chemical biology in pharmacy: molecular biology of diseases and in-vivo transgenic models, genomic protein targets and recombinant therapeutics Rational Drugs design. Chemical biology and molecular diversity. DNA/ RNA targeted therapeutics. **(06 hrs)**

Introductory Bioinformatics: Biological databases, sequence analysis, protein structure, genetic and physical mapping, applications of bioinformatics in pharmacy. **(03 hrs)**

s Recommended

Nelson, D. L. and Coy, M. M. "Lehninger's Principles of Biochemistry" Worth Publisher, New York.

Karp, G., Cell Molecular Biology.

Crommelin, D. J. A., and Sindelar R. D. Pharmaceutical Biotechnology.

4. Termpleton N. S. and Lasic, D. D. Gene Therapy.
5. Benjamin Lwwin, Genes.
6. Watson and Trooze, Recombinant DNA Techniques
7. Lesk A. M. "Introduction to Bioinformatics" Oxford University Press (Indian Ediction) New Delhi
8. Waston, Molecular Biology of Cell
9. Old and primrose, Principles of Gene Manipulations.
10. Watson, J. D. Frana, Duelette, B. F. Bioinformatics
11. Baxevanis, A. D. Gilman, M. Recombinant DNA Technology
12. Alberts, B. Johnson, A, Lewin, J. Raff M, Roberts, K. Walter, P. Molecular biology of the cell.
13. Paul, W.E. Fundamental of Immunology.
14. Klug W. S. Cummings M. R. Essential of Genetics
15. Glick, B. R. and Pasternak, J.J. "Molecular Biotechnology" ASM Press Washington.
16. Walker, J. M. Ripleyj, R. Molecular biology and biotechnology
17. Bolton, S. Pharmaceutical Statistics.
18. Rastogi, S.C. Mendiratta, N. and Rastogi P. "Bioinformatics-Concepts, Skills and Applications" CBS Publishers and Distributors, New Delhi.