NORTH MAHARASHTRA UNIVERSITY, JALGAON
STRUCTURE AND SYLLABUS FOR M.PHARM

North Maharashtra University, Jalgoan offers Master of Pharmacy (M. Pharm) Course in the following specializations:

1) Pharmaceutical Chemistry
2) Pharmacognosy
3) Quality Assurance

Duration:

The duration of Master of Pharmacy (M. Pharm) Course is of 24 months, divided into four semesters, each semester of 6 months.

Eligibility For Admission To M. Pharm. Course:

The candidate seeking admission to M. Pharm. Course must have passed B. Pharm. Degree Examination of any statutory/recognized University with at least 60% of aggregate marks or equivalent grade (55% marks for S.C./S.T. candidates). Teachers and sponsored

Admission to M. Pharm. Course

The admission should be made as per Govt resolution dated 30th May 1996, modified on 3rd September 1998 and corrected on 21st July 2001.

Fees:

The Tuition fees, other fees and deposits like Library and Laboratory deposit will be as prescribed by the University from time to time.

Grant of Terms:

The student who has satisfactorily completed the prescribed requirements of the course and has kept at least 75% attendance at theory classes and practical (if any) separately for each subject will be granted terms.

Scheme of Teaching:

The scheme of teaching will be as per :

Annexure I A (Pharmaceutical Chemistry)
Annexure I B (Pharmacognosy)
Annexure I C (Quality Assurance)

Scheme of Examination:

There shall be a University examination at the end of each semester. The examination shall be as per the scheme mentioned in Annexure I A/B/C. The student with a backlog of maximum two heads of previous semesters can keep terms and appear for the next semester examination.

A candidate who has failed to pass fourth Semester Examination will be required to keep minimum one fresh Semester and resubmit the revised dissertation, give a seminar and appear for Viva-voce examination.

Standard of Passing:

(a) The student will be declared to have passed first and Second Semester Examinations, if he has obtained at least 45% marks separately in all Theory Papers and Practical and at least 'C' Grade in Seminar. In addition, he should

have obtained at least 50% of the aggregate marks assigned to the examination of each semester.

(b) To pass Third and Fourth Semester Examination, the student must have obtained at least 50% of the total marks and at least 'C' grade in Seminar.

Exemption:

A student who has obtained at least 50% marks in theory paper/s and/or practical/s shall be exempted at his/her option from appearing for the same. The passing of student with exemption will not affect his/her class of passing of examination.

Seminar:

The student will have to give one seminar in each Semester.

Evaluation of Performance in Seminar:

The performance of student in seminars will be evaluated by the Seminar Evaluation Committee consisting of the guide and at least one more teacher.

"A"	-	Excellent
"B"	-	Very Good
"C"	-	Good
"D"	-	Poor/fair

The student will be considered to have passed in seminar provided he/she has obtained at least "C" grade. If "D" grade is allotted to the student he will be given one more chance to improve the grade in the same semester.

The grade awarded to the student in the seminar will be shown separately in his statement of marks of the concerned semester.

Award of Class:

A Class will be awarded to the student on the basis of aggregate marks obtained by him/her in all semesters of M. Pharm.

First Class with Distinction	-	70% and above marks
First Class	-	60% and above, but less than 70% marks
Higher Second Class	-	55% and above, but less than 60% marks
Second Class	-	50% and above, but less than 55%

Dissertation:

The topic for the dissertation shall be assigned to him/her by the Guide within two months from the date of the commencement of the first semester. Every student before appearing for the M. Pharm. fourth Semester Examination is required to submit 3 typewritten copies of the Dissertation (duly certified by the Guide and Principal) to the University for evaluation.

The student will not be allowed to submit his/her dissertation before the completion of 23 months from his/her date of registration. However, he/she will have to submit the same within a period of one month after the end of the fourth Semester.

Evaluation of Dissertation:

The Dissertation submitted by a student will be evaluated jointly by:

1) Internal Examiner (Guide)
2) External Examiner (Appointed by the University)

M. PHARM. COURSE STRUCTURE
SPECIALIZATION: QUALITY ASSURANCE

ANNEXURE -I C

Semester	No. and Title of Paper	Scheme of Teaching Hours/week		Scheme of Examination				Total
				Theory		Practical		
		Lectures	Practicals	Hrs.	Marks	Hrs.	Marks	
I	Quality Assurance Techniques –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	Quality Assurance Techniques –I	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) Scintific contents	= 20
(b) Experimental Work	= 60	(b) Presentation / Communications	= 20
(c) Scintific Contents	= 20	(c) Discussion	=20
(d) Presentation/ Communication	= 40	(d) Report	=40
(e) Result/ Conclusion	= 50		
Total Marks	= 200	Total Marks	=100

M. PHARM. COURSE STRUCTURE
SPECIALIZATION: PHARMACOGNOSY

ANNEXURE -I B

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. Pharmacognosy –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. Pharmacognosy –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 Reserach 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) Scintific contents	= 20
(b) Experimental Work	= 60	(b) Presentation / Communications	= 20
(c) Scintific Contents	= 20	(c) Discussion	=20
(d) Presentation/ Communication	= 40	(d) Report	=40
(e) Result/ Conclusion	= 50		
Total Marks	= 200	Total Marks	=100

NORTH MAHARASHTRA UNIVERSITY, JALGAON
STRUCTURE AND SYLLABUS
(w.e.f. Academic year 2002 –03)

M. PHARM. COURSE STRUCTURE
SPECIALIZATION: PHARMACEUTICAL CHEMISTRY

ANNEXURE -I A

Semester	No. and Title of Paper	Scheme of Teaching Hours/week		Scheme of Examination Theory		Practical		Total
		Lectures	Practicals	Hrs.	Marks	Hrs.	Marks	
I	Adv. Pharm. Chemistry –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. Pharm. Chemistry -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) Scintific contents	= 20
(b) Experimental Work	= 60	(b) Presentation / Communications	= 20
(c) Scintific Contents	= 20	(c) Discussion	=20
(d) Presentation/ Communication	= 40	(d) Report	=40
(e) Result/ Conclusion	= 50		
Total Marks	= 200	Total Marks	=100

Advanced Analytical Techniques
ADVANCED PHARMACEUTICAL ANALYSIS
(3 Hrs/Weeks)

1) Spectroscopic Methods – Introduction, Applications and Structure Elucidation using UV, IR, NMR, Mass Spectrometry with examples.
2) Separation Techniques – Theory, Instrumentation, and Applications of GLC, HPLC, HPTLC, Chiral Chromatography, Ion Pair Chromatography.
3) Thermal Analysis – Theory, Instrumentation and Applications of Thermogravimentric analysis, Differential Thermal Analysis, Differential Scanning Calorimeter.
4) Immunochemical Techniques – Immunoelectrophoresis, Immunoprecipitation, ELISA; Radioimmunoassays.

Advanced Analytical Techniques
ADVANCED PHARMACEUTICAL ANALYSIS
(3 Hrs/Weeks)

PRACTICALS:

1) Experiments based on UV, FT-IR, HPCL, GC and DSC
2) ELISA Test/LAL Test
3) Estimation of drugs in biological fluids.
4) Validation of analytical methods

RECOMMENDED BOOKS:

1) Skoog: Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2) M. Orchin and H. H. Jaffe – Theory and applications of ultra violet spectroscopy (John Wiley and Sons, N. Y.)
3) Silverstein, Basserler, Moriil – Spectrometric identification of organic compounds (John Wiley and Sons, N. Y.)
4) Willard, Merritt, Dean – Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5) J. R. Dyer – Applications of Absorption Sectroscopy of Organic compounds (Prentic Hall, London)
6) C. N. R. Rao – Chemical application of Infra-red spectroscopy (Academic press, N.Y.)
7) Higuchi: Instrumental Methods of Analysis (CBS Publishers)
8) Analytical Chemistry by open learning series
9) R. J. Hamilton – Introduction to High Performance Liquid chromatography, (Chapman and hall, London).
10) Ewing – Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)

ADVANCED PHARMACEUTICAL CHEMISTRY –I
3 (Hrs/Weeks)

1) MOLECULAR BASIS OF DRUG ACTION:

a) Receptor: Drug Receptor Interaction.

1) Basic ligand concept, agonist, antagonist, partial agonist, inverse agonist.
2) Receptor Theories – Occupancy, Rate & Activation Theories.
3) Receptor Binding Assays, Determination of Bmax and Kd by transforming data with Hill plot and Scatchered plot.
4) Above concepts with special reference to Opioid, Histaminergic, Adrenegric and GABA nergics receptors.

b) Enzyme Inhibition –

1) Enzyme structure: primary, secondary, tertiary and quaternary.
2) Enzyme Kinetcis
3) Enzyme Inhibitors – Reversible, Irreversible, Keat inhibitors, Transition state analogs.
4) Enzyme Inhibitors as drugs – ACE, leukotrienes, Lipoxygenase, Aromatase, Xanthine oxidase, DNA Polymerase Inhibitors, HIV – Protease/Reverse Trascriptase, Integrase and Cytochrome P-450 Inhibitors.

c) Drug binding to nucleic acid: Antimalarial, anti-cancer, antiviral

2) Design and Application of Prodrugs-

a) Prodrug Concept
b) Prodrugs of various functional groups like carbonyl, hydroxyl, amide, amines.
c) Application of prodrug approach to:
   i) Improvement of bioavailability
   ii) Prevent first pass metabolism
   iii) Reduction of side effects
   iv) Prolong duration of action
   v) Site specific delivery

3) Synthon Approch

a) Definition of terms – disconnection, synthon, functional group interconversion (FGI).
b) Basic rules in Disconnection
c) Use of synthon approach in synthesis of following compounds:
   Trimethoprim, Terfenadine, Ibuprofen, Propanolol, Fentanyl, Ciprofloxacin, Cimetidine, Piroxicam, Rosiglitazone, Diclofenac, Captopryl, Nifedipine, Losartan.

4) Recent Advances and Trends in the above mentioned categories of drugs.

COMMENDED BOOKS:

1) Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)
2) Foye: Principal of Medicinal Chemistry (Varghese & Co.)
3) Ledinicer: Organic Drug synthesis Vol. 1,2,3,4 (John Wiley & Sons N.Y.)

4) Ariens: Medicinal Chemistry Series
5) Ellis and West: Progress in Medicinal Series
6) Butterworther: Progress in Medicinal Chemistry Series
7) Wilson and Gisvold's Text book of Medicinal Chemistry (J. B. Lippincoff cam)
8) Stuart Warren: Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9) Comprehensive Medicinal Chemistry – Series – I-VI (Academic Press)

ADVANCED PHARMACEUTICAL CHEMISTRY –I PRACTICAL (6 Hrs/Weeks)

1) Study and applications of enzymes Kinetics, Inhibition and Immobilization
2) Determination of partition coefficient
3) Determination of pKa value,
4) Synthesis of drugs mentioned in the theory using basic operations like molecular distillation, fractional crystallization, purification by column chromatography, Preparative TLC
5) Synthesis of drug using synthon approach.
6) Structure confirmation by spectroscopic studies
7) Mixture analysis of 2/3 organic compounds

Recommended Books:

1) Organic Synthesis: Fieser and William Son (CBS Publisher)
2) Mann and Saunters, practical Organic Chemistry (Orient Longman)
3) AI Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)

ADVANCED PHARMACEUTICAL CHEMISTRY – II (3 Hrs/Weeks)

Combinatorial Chemistry
Introduction
Combinatorial approaches
Chemical Peptide and small molecule libraries;
Application, methodology
Combinatorial Organic Synthesis
Assays and Screening of Combinatorial libraries
Introduction to High Throughputs Screening (HTS)

Chiral Technology:
Introduction to Chirality and Techniques used: Assymmetic synthesis of Dilitiazim, Timolol, Vitamin C, Ampicillin, Dextropropoxyphen, Thienamycin, Citranalol, Propranolol, Atenolol, Naproxen.

3) ·rganisms in Drug Synthesis and Development -
·ıbial conversions of drugs like steroids, prostaglandins, antibiotics, enzyme immobilization Techniques.
4) Agents used in Neurodegenerative diseases: Like Alzheimers, Parkinsonism
5) Agents used in treatment of AIDS – Life cycle of HIV and drugs used.
6) Proteins and Peptide drugs:
Chemistry, structure and stability. Reactivity of proteins and peptides. Different ways to synthesize these drugs-study of Insulim, Relaxin, Somatostatin, DNAse Interferon.
7) Recent Advances and Trends in the above mentioned categories of drugs.

RECOMMENDED BOOKS

1) Burger: Medicinal Chemistry)John Wiley & Sons N. Y.)
2) Foye: Principles of Medicinal Chemistry (Varghese & Co.)
3) Ledinicer: Organic Drug synthesis Vol. 1,2,3,4 (John Wiley & Sons N.Y.)
4) Ariens: Medicinal Chemistry Series
5) Ellis and West: Progress in Medicinal Chemistry Series
6) Butterworther: Progress in Medicinal Chemistry Series
7) Wilson and Gisvold's: Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8) Stuart Warren: Organic Synthesis – The Discommection Approach (John Wiley & Sons)
9) Comprehensive Medicinal Chemistry – Series – I-V1 (Academic Press)

ADVANCED PHARMACEUTICAL CHEMISTRY – II
(6 Hrs/Weeks)

PRACTICALS:

1) Asymmetric synthesis
2) Application of partition coefficient, pKa, steric factors, electronic factors in QSAR studies with example. Use of statistical regression analysis.
3) Microbial conversion for drug synthesis
4) Resolution of racemic mixture
5) Mixture analysis of 2/3 organic compounds.
6) Synthesis of compounds using ¾ steps, structure confirmation by spectroscopic methods.
7) Determination of partition coefficient, pka

Recommended Books:

1) Organic Synthesis; Fieser and William Son (CBS Publishers)
2) Mann and Saunters, Practical Organic Chemistry (Orient Longman)
3) A I Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)

ADVANCED PHARMACOGNOSY – I
(3 Hrs/Week)

1) **A) General Research Methodology.**
B) Information Retrieval system of Herbal Drugs.
Literature survey of following therapeutic groups: (Each group 3-4 drugs)

i) Immunomodulators
- *a) Withania somnifera*
- *b) Centella Asiatica*
- *c) Emblica asiatica*
- *d) Ocimum sanctum*

ii) Anti-Peptic ulcer
- *a) Glyceriza Root*
- *b) Azadirachta indica*
- *c) Gingiber officinalis*

iii) Hepatoprotectives
- *a) Silibum marianum*
- *b) Phyllanthus niruri*
- *c) Picrorrhiza kurroa*
- *d) Andrographis paniculata*

iv) Anti-cancer
- *a) Taxus species*
- *b) Camptotheca acuminata*

v) Anti-Fertility
- *a) Emblica ribes*
- *b) Azadirachta indica*
- *c) Gossypium species*

vi) Nervine Tonics
- *a) Centella asiatica*
- *b) Acorus calamus*
- *c) Valeriana wallichi*

i) Anti-AIDS
- *a) Curcuma longa*
- *b) Areca catechu*
- *c) Thea sinensis*

Review of Natural Sweeteners: Dyes & Pigments, Preservatives

Volatile oils - Commercial significance:
A) Review of Indian Spices Industry
B) Perfumery Industries.

Herbal Drug Regulatory affairs

ommended Books: (For Advanced Pharmacognosy I, II & III Theory)

1) Introduction to spices, plantation crops, medicinal and aromatic plants: N. Kumar et al, oxford & IBH Publishing Co. Pvt. Ltd. New Delhi, 1997.

2) Herbal Drug Industry: R.D. Chaudhari, Eastern Publishers, New Delhi 1996
3) Various journals related to spices, perfumes, food & nutrition.
4) Wealth of India, CSIR, New Delhi (Related Volumes)
5) Cultivation & Utilization of medicinal plants: Atal & Kapoor, RPL, Jammu.
6) Cultivation & Utilization of aromatics plants: Atal & Kappor, RPOL, Jammu
7) Drug & Cosmetic act, (with latest amendments including Ayurvedic GMP), Govt. of India.
8) Various journals related to medicinal plants.
9) Pharmacognosy : Trease W. C., Evans G. E. Bailliere & Tindall, London, 14th Edn.
10) British Herbal Pharmacopoeia, (Vol. I, II & III) Her Majesty's Services, U. K.
11) Ayurvedic formulary of India, Govt. of India. 1962.
12) Research in Education: John W. Best & James V. Kahn, Practice Hall of India Pvt. Ltd. New Delhi, 1996
13) Various Research Journals on Medicinal natural products.

ADVANCED PHARMACOGNOSY-I PRACTICAL
(6 Hrs/Week)

1) Micro study using microtome and preparation of permanent slides. (Double staining technique)
2) Evaluation and standardization of a given herbal drug by physical, chemical and biological methods.
3) Isolation of total oleo-resin from ginger
4) Isolation of pectin
5) Isolation of papain
6) Isolation of natural dye anthocyanin
7) Isolation of natural sweetener glycyrrhizin from Glycyrrhiza glabra
8) Determination of protein content
9) Isolation and estimation of total phenolics
10) Extraction of volatile oil and its formulation into perfume
11) Isolation of 'Eugenol' from clove oil.

commended Books:

1) Various pharmacopoeias
2) Practical Pharmacognosy: Kokate C.K., Vallabh Prakashan, New Delhi
3) Practical Pharmacognosy: Khandelwal K.R., Nirali Prakashan, Pune
4) Phytochemical methods: J. B. Harborne
5) Thin layer chromatography: Stahl

ADVANCED PHARMACOGNOSY-II
(3 Hrs/Week)

1) Isolation, Purification and instrumental interpretation of Phytoconstituents:

Caffeine	Atropine
Vinblastine	Curcumin
Hesperidin	Taxol
Ergometrine	Digoxin
Diosgenin	

2) Chemotaxonomy of Flavonoids and Terpenoids.
3) Marine drugs and their discovery
4) Review of various Phytoconstituents used as prototypes for therapeutically active constituents:

Recommended Books: (For Advanced Pharmacognosy I, II & III Theory)

1) Introduction to flavonoids: Bruce A. Bohm, harwood academic publishers, 1998.
2) Herbal Drug Industry: R. D. Chudhary, Eastern Publishers, New Delhi 1996.
3) Wealth of India, CSIR, New Delhi (Related Volumes)
4) Cultivation & Utilization of medicinal plants: Atal & Kapoor, PRL, Jammu.
5) Cultivation & Utilization of aromatic plants: Atal & Kapoor, PRL, Jammu.
6) Various journals related to medicinal plants.
7) Pharmacognosy: Trease W.C. Evans G. E. Bailliere & Tindall, London, 14th edn.
8) Pharmacognosy: Kokate, Purohit, Gokhale, 15th edition, Nirali Prakashan, Pune
9) British Herbal Pharmacopoeia, (vol. I, II, & III) Her Majesty's Services, U. K.
10) Phytochemical methods: J. B. Harborne
11) Various Research Journals on Medicinal natural products.

ADVANCED PHARMACOGNOSY – II
Practical (6 Hrs/Week)

1) Selection, Authentication, Herbarium Preparation, Macroscopy, Microand powder characteristic study of official herbal drugs.
2) Estimation of following phytopharmaceuticals:
   a) Total Triterpene acids in Boswellia serrata
   b) Total Phenolic acids as Benzoic acid from Benzoin
   c) Total Tropane alkaloids from Datura/Hyoscyamus tinctures
   d) Estimation of Adrographolide from Andrographis paniculata
   e) Column chromatographic isolation of psoralen from *psoralea corylifolia* seed extract
3) Study of UV and Visible spectra data of some natural products.
4) Study of IR spectra data of some natural products.

5) Preparation of traditional drug formulation mentioned in the Advanced Pharmacognosy II Theory and their standardization.
6) Preparation of Herbal drug formulations mentioned in Advanced Pharmacognosy –III theory and their standardization.

Recommended Books:

1) Practical Pharmacognosy, Khandelwal. K. R. 7th Ed., Nirali Prakashan, Pune 2000
2) Pharmacopoeia of India, Ministry of health, Govt of India 1996
3) Practical Pharmacognosy, Kokate C. K. Vallabh Prakashan, New Delhi
4) Indian Herbal Pharmacopoeia. Vol. III IDMA, Mumbai
5) Thin Layer Chromatography – E/ Stahl, 2nd Edition 1969
6) Ayurvedic Pharmacopoeia of India: Govt. of India.
7) Spectroscopic Identification of Organic compounds, Silverstein R. M. Bassler G. C. and Morril T. C. 5th Ed. John Wiley and Sons Inc. 1991.

QUALITY ASSURANCE TECHNIQUES – I

1. Product development stage documentation.
2. Manufacturing documents. cleaning methods retention samples. records.
3. Quality Control Documentation.
4. Batch release documents.
5. Retentions of records.
6. Validation of equipments.
7. Validation of processes.
8. Validation of products.
9. Application of computer in store management. production and control.

QUALITY ASSURANCE TECHNIQUES – I
Practical(3hrs/week)

1. Learning different programming languages, writing programmes for simple calculation, statistical analysis, data acquisition. processing and retrievals.
2. Physical and Chemical Examination of plastic containers.
3. Labels. cartons and other printed materials.

Quality Assurance Techniques – II
Theory (3hrs/week)

1. An understanding of the concepts of quality assurance good manufacturing practice and quality control as applied to the pharmaceutical industry.
2. Rules governing the manufacture of medicine in India.
3. Good laboratory practice (GLP).
4. Inspection from regulatory authorities.
   Drug and Cosmetics Act and Rules, Narcotic Drugs and Psychotropic Substances Act and Rules, Drugs and Magic Remedies Act, Environment Protection.
5. The role of quality assurance in raw materials, product development, pre-production manufacture, sales, personnel in quality Assurance programme ISO 9000 to 9004 and their applications to pharmaceutical industry.

QUALITY ASSURANCE TECHNIQUES – II
Practicals (3 hrs/week)

1. Animal experiments for determination of potency and toxicity of drug substances and dosage forms, assessing safety of packaging materials.
2. Experiments involving use of microbiological techniques in analysis of drug substances and dosage forms.
3. Practice in developing of analytical method of drug substances.

ELECTIVES

1. STERILE PRODUCT FORMULATION AND TECHNOLOGY
(3 Hrs/Week)

A) FORMULATIONS:

1) **Preformulation:** Physico-chemical properties of materials used in parenteral formulations, selection of polymeric components, selection of packaging components.
2) **Formulation of SVP and LVP:** Requirement, components, materials, Pharmacopoeial requirements, special types of parenterals such as suspensions, emulsions, dried forms, sterile diagnostics and radiopharmaceuticals.
3) **Ophthalmic Products:** Ocular anatomy and physiology relevant to ocular drug delivery, ocular pharmacokinetics, conventional ophthalmic products, ocular inserts, particulate and liposomal drug delivery, protein and peptide delivery.
4) **Sustained Release Parenterals:** Liposomes, and niosomes, nanoparticles, proteins and peptides, implants, loaded erythrocytes.

TECHNOLOGY:

·nufacturing of Parenterals:

1) Environmental Control: Temperature and humidity control, air handling systems and their validation.
2) Industrial sterilization: Large scale sterilization processes, process selection, specifications, development and validation of process and equipments.
3) Guidelines: Overview of GMP and regulatory guidelines.

Recommended Books:

1) K.E. Avis, H. A. Liberman and Lachman; Pharmaceutical dosage forms: Parenteral Medications; Vol. 1,2,3 Marcel Dekker.
2) S. J. Turco; Sterile dosage forms: their preparation and clinical application; Lee and Febiger
3) N. K. Jain; Controlled and novel drug delivery; CBS Publication.
4) J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamental and Applications; Marcel Deker.
5) F.J. Carleton and J.P. Agalloco; Validation of aseptic pharmaceutical processes; Marcel Dekker.
6) L. A. Trissel; Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.
7) N.A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.

2. NOVEL DRUG DELIVERY SYSTEMS
(3 Hrs/Week)

1) **Basic considerations of novel drug delivery systems:** Biopharmaceutical aspects and technology transfer of controlled release dosage forms.
2) **Oral drug delivery systems:** Based on different control mechanism such as Osmotic pressure, membrane controlled, pH, ion-exchange, gastrointestinal transit etc.
3) **Mucosal drug delivery:** Physiological, biopharmaceutical consideration, formation and models used.
    A) Buccal: Physiology and permeability of oral mucosa, penetration enhancement, drug delivery systems and in-vitro and in-vivo techniques.
    B) Nasal: Anatomy and physiology of nasal mucosa, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation.
    C) Pulmonary: Structure and function of pulmonary system, factors affecting deposition in lungs. Dosage forms: Nebulizers, pressurized inhalation aerosols, aerosol powder devices.
    D) Rectal: Physiology, advantages, dosage forms and evaluation models.
4) **Intrauterine and intravaginal drug delivery devices.**
5) **Ocular delivery:** Ocular delivery mechanism and development of ocular controlled release.
6) **Transdermal drug delivery:** Permeation through skin, permeation enhancers, technologies nanoparticles.
7) **Microencapsulation:** various technique, parameters affecting microcapsules, microcapsule stability, mechanisms, manufacturing equipments.
8) **Advances in drug delivery:** Pulsatile, colon specific, intra-arterial, noncorneal drug delivery and systemic delivery of ophthalmic diseases.

Recommended Books:

1) P. Tyle; Drug Delivery Devices, fundamental and applications; Marcel Dekker.
2) Morton Rosoff; Controlled release of drugs; VCH Publishers.
3) Osborne, and Amann; Topical drug delivery formulations; Marcel 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 Publication, New Delhi
8) P. Johnson and J. G. Lloyd – Jones; Drug delivery systems; VCH Publisher
9) P. Tyle and B. P. Ram; Targeted therapeutics systems; Marcel Dekker.
10) C.G. Wilson & N. Washington; Physiological Pharmaceutics; Ellis Horwood Limited.
11) H.S. Bean, A.H. Beckett, and J.E. Carless; Advances in Pharmaceutical Sciences; Vol. 5, Academic Press.
12) R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivry; Marcel Dekker
13) T.J. Roseman and S.Z. Mansdorf; Contolled release delivery systems; Marcel Dekker
14) A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology; Marcel Dekker.
15) J. Kreuter; Controlled drug delivery system; Marcel Dekker
16) P.B. Deasy; Microencapsulation and related drug processes; Marcel Dekker.

3. BIOPHARMACEUTICS AND PHARMACOKINETICS (3 Hrs./Week)

1) **Absorption:** Cell membrane, absorption mechanisms, oral drug absorption, pH-partition hypothesis. Factors affecting: Physico-chemical, dosage form related, patient related. Drug absorption through other routes; transdermal, nasal, buccal, ocular and sublingual. In-vitro, in-situ and in-vivo models for drug absorption studies.
2) **Distribution:** Tissue permeability of drug, barriers to distribution of drugs. Factors affecting drug distribution, physicochemical properties of drugs, volume of distribution, Drug-protein binding, drugs tissue binding, factors affecting protein drug binding. Kinetics of drug protein binding, significance of drug tissue binding.
3) **Metabolism:** Drug metabolism, organs and enzymes, chemical pathways, Phase-I and Phase-II reactions. First pass effect, factors affecting.
4) **Excreation:** Renal and nonrenal routes of drug excretion, concept of clearance. Factors affecting excretion mainly renal excretion.
5) **Pharmacokinetics:** Pharmacokinetics models, Laplace transformations, concept of compartment modeling:
    1) One compartment model: intravenous injection, intravenous infusion, first order absorption (urinary and plasma data)
    2) Multicompartment models. Intravenous injection, intravenous infusion, first order absorption, multidosing data.
    3) Non-linear Pharmacokinetics Michaelis – Menten's kinetics, estimation of Km and Vm area under curve, enzyme induction.

4) Non compartmental analysis – statistical moment theory
5) Application of pharmacokinetic: Multiple dosing, sustained drug delivery, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronopharmacokinetics.

6) **Bio-availability and bioequivalence:** Study design, protocols, regulatory requirements and statistical consideration.

Recommended Books:

1) J. B. Blanchard, R. J. Sawchul and B.B.Brodie; Principle and Perspectives in drug Biovailability; K. Karger Publication.
2) M. Gibaldi and Perrier; Pharmacokinetics; Marcel Dekker.
3) M. Gawland and T.N. Tozer; Clinical Pharmacokinetics; Waverly Publicatins.
4) P. Jenner and B. Testa; concepts in drug metabolism; Marcel Dekker
5) D. M. Brmhankar and S. B. Jaiswal; Biopharmaceutics and pharmacokinentis A Treatise; Vallabh Prakashan.
6) Pierre Labaune: Hand book of Pharmacokinetics; John Wiley and Sons.
7) B. Testa: Advances in drug research; Vol. 19] academic press.
8) R. E. Notari; Biopharmaceutics and clinical Pharmacokinetics; Marcel and Dekker.

4. INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT (3 Hrs/Week)

1) **Pilot plant scale:** up, pilot plant design: tablets, capsules liquid orals, parenteral and semisolid preparations.
   Basis requirement for design of product, facility equipments selection, personnel, Pharmaceutical process validation for various products.
2) **Quality Assurance:** GMP consideration, quality assurance and process control. Total quality management and productivity. ISO 9000 series salient features.
3) **Optimization techniques:** Optimization parameter, classical optimization, statistical design and applied optimization methods.
4) **Production planning:** Plant site selection, layout and organization of pharmaceutical industries. Vedor development capacity (plant, machine human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix.
5) **Drug and Cosmetics Act:** Requirement related to manufacture and sale of drugs.
6) **Machinery Engineering:** Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handling for various pharmaceutical products.
7) **Safety:** Industrial hazards due to fire, accident, mechanical and electrical equipment chemical and pharmaceutical, monitoring and preventive system.
8) **Effluent testing and Treatment:** For pharmaceutical industry.

9) **Automation:** Flexible manufacturing system, computer control system: data acquisition, distributed control and centralized control system. Typical models for solid and liquid manufacturing.

Recommended Books:

1) P. R. Watt; Tablet machine instrument in pharmaceuticals: John Wiely and Sons.
2) B. Rothery; ISO 14000 and ISO 9000; Grower.
3) G. C. Cole: Pharmaceutical production facilities, Design and applications; Taylor and Francis
4) J.R. Berry and R. A. Nash; Pharmaceutical process validation; Marcel Dekker
5) S. Bolton; Pharmaceutical statistics; Marcel Dekker.
6) S.H. Will and J.R. Stoker; good manufacturing practices for pharmaceuticals; Marcel Dekker.
7) R. F. Brewe; Design of Experiments for process improvement and quality assurance; Narosa.
8) A. Jaiswal; Management of quality control and standardization: Kanishka Publisher, New Delhi
9) D.H. Stamatis: Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
10) P. Gilson, G. Green halgh and K. Kerr; Manufacturing management; Chapman and Hall.
11) S.S. Rao; Optimization theory and applications; Wiley Eastern Limited.
12) J. F. Despautz: Automation and validation of information in pharmaceutical processing; Marcel Dekker.
13) J.M. Juran and A.B. Godfrey; Juran's Quality Handbook; McGraw Hill.
14) S. N. Katju's Law and drugs; Law Publishers (I) Pvt. Ltd.

5. PACKAGING TECHNOLOGY
(3 Hrs/Week)

1) **Elements of packaging:** Purpose, types of packaging material: primary and secondary and special types.
2) **Material:** paper and paper board, films and foils, coating and laminations, Bag and pouches; glass; plastics, metal, Sterilization of primary packaging material by gamma irradiation. Aerosols, corrugated boxes.
3) **Labeling:** printing, adhesives and code marking
4) **Closures and adhesive:** Caps, stoppers, plugs, child resistant caps, Roll on dispenses, adhesives.
5) **Quality Control and Safety and Environmental consideration.**

ommended Books:

1) J. F. Hanlon; Handbook of package Engineering; Mc-Graw Hill book Company.
2) Lockhart H; Packaging pharmaceutical and health care.
3) K. Harburn; Quality control of Packaging Material in the Pharmaceutical Industry; Marcel Dekker.

6. FERMENTATION TECHNOLOGY
(3 Hrs/Week)

1) **Industrial Microorganism:** Source, characteristic, growth and genetics.
2) **Development of Industrial Fermentation Processes:** Screening, detection and assay of fermentation products stock cultures, fermentation media, inoculum preparation, scale up of fermentations, increasing product yield, fermentation economics.
3) **Industrial Fermentor:** Batch and continuous operation, requirements and design of fermentor, control mechanisms for temperature, pH and foam. Sterilization of fermentation equipment. Tank agitators, spargers, heating and cooling equipment, Material for construction.
4) **Typical Fermentation Process:** Antibiotic fermentation properties, biosynthesis and Fermentation of antibacterial antibiotics – penicillins, tetracyclines, aminoglycoside, chloramphenicol and macrolides. Antifungals – Griseofulvin. Antiviral – bacitracin, hamycin. Antibiotic production by immobilized living cells.
   Enzyme fermentation: Amylases, proteolytic enzymes. Other Fermentation : Acctonebutanol, citric acid, glycerol, industrial alcohol, yeast and Vitamins.
5) **Downstream Processing:** Unit operation in downstream processing.
   a) Harvesting: Sedimentation, centrifugation, filtration.
   b) Cell Disintegration: Non-mechanical methods such as physical chemical and enzymatic treatment and Mechanical methods such as wet milling, high pressure homogenization, pressure extrusion and sonification.
   c) Clarification of crude extract.
   d) Product Enrichment: Precipitation, ultra-filtration, extraction.
   e) Chromatography: Gel filtration, ion exchange, hydrophobic and affinity type.

Recommended Books:

1) E. J. Vandamme; Biotechnology of Industrial Antibiotics; Marcel and Dekker.
2) H. J. Rehm and G. Reed; Biotechnology; Verlag Chemie.
3) L. E. Casida; Industrial Microbiology; Wiley Eastern Limited.
4) G. Reed; Prescott and Dunn's; Industrial Microbiology; The AVI Publications.
5) Patel; Industrial Microbiology

7. COSMETICOLOGY
(3 Hrs/Week)

1) **Physiological consideration:** Skin, hair, nail and eye – in relation to cosmetic application.
2) **Rheology of cosmetic:** Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.
3) **Manufacturing techniques:** cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

4) **Evaluation of cosmetics:** Performance, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antipersirants, sunscreen and antiaging products.
5) **Clinical safety testing:** Irritation, sensitization, photo-irritation, photo-allergy, ocular irritation and protocols for the same.
6) **Regulatory requirements:** Manufacturing and sale of cosmetics
7) **Herbal cosmetics:** Formulation development
8) **Packaging:** Package development and design for cosmetics including aerosol packs
9) **Advances in cosmetics:** Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.

Recommended Books:

1) J. Knowlton and S. Rearece: Handbook of cosmetic sciences and technology; Elsevier science publisher.
2) J. B. Wilkinsin and R. J. Moore; Harry's Cosmetology Longman Science and Technical
3) S. N. Katju's: Law of Drugs; Law Publishers (I) Pvt. Ltd.
4) E. G. Thomssen; Modern cosmetics; Universal Publishing Cop.
5) M.S. Balsam and E. Sagarin; Cosmetics, sciences and technology; John Wiley and sons.
6) R. L. Elder; cosmetic ingredients; their safety assessment; Pathotox
7) H.R. Moskowitz; Cosmetic Product Testing; Marcel Dekker
8) W. C. Waggoner; Clinical safety and efficacy testing of cosmetic; Marcel Dekker.
9) C. G. Gebelein, T.C. Cheng and V. C. Yang; Cosmetic and pharmaceutical applications of polymers; Plenum
10) L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle press.
11) W. A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3 chapman and Hall
12) Dr. Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

8. POLYMERS IN PHARMACEUTICALS
(3 Hrs/Week)

A) STUDY OF POLYMERS:

1) **Classification of polymers:** synthesis of polymers, general methods of preparation of polymers like solution bulk, suspension and emulsion polymerizations. Properties of following commonly used polymers: starch, glelatin, albumin, Cellulose derivatives, acrylates and polozamers.
2) **Characterization of polymers:** Molecular weight and Molecular weight distribution of polymers, flow characteristics, crystallinity, solubility and thermodynamic of polymers solutions biodegradability and biocompatibility testing of polymers.

B) APPLICATIONS OF POLYMERS:

Acrylic latex system and their applications, Biodegradable polymers and their application in parenterals, application of polymers in conventional and new drug delivery system.

Recommended Books:

1) J. Brandrup, E.H. Immergur; Polymer Handbook; John Wiley and Sons.
2) Charles G. Gebelein, T.C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
3) D.S. Soane; Polymer Applications of Biotechnology; Prentice Hall Inc.
4) J. R. Robison and V. H. Lee; Controlled Drug delivery- Fundamentals and Applications; Marcel Dekker.
5) N.K. Jain; Controlled and Novel Drug Delivery; CBS publication.
6) P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press
7) A. F. Kydonieus: Controlled Release Technologies: Methods, Theory and Applications, Vol. I & II CRC press Inc.

9. BULK DRUG TECHNOLOGY
(3 Hrs/Week)

a) Stoichiometry and its important in the manufacturing of drugs
b) Discussion in the following process (reaction types in relation to manufacturing of dugs)
Acetylation, Nitration, Sulphonation, chlorosulphonation, Oxidation, Reduction, alkylation, halogenation, Carboxylation, Decarboxation, Esterification, addition, epoxidation and important rearrangements.

Unit process: Study of the following chemical process (with reference to reagents, mechanisms, equipments and manufacture of drugs given below): Acylation, etherification, alkylation, amination halogenation, hydrolysis, nitration, oxidation, reduction.

Further discussion on unit operations important to drug synthesis e.g. mixing, distillation, drying, filtration and centrifugation, evaporation, crystallization, counter current extraction Effluent treatment and Pollution control.

Principles and design of the reactors – Factors to be considered (including material selection) construction of flow diagrams – selection of equipment.

Detailed manufacturing aspects, inclusive of processes and operations involved for:
Aspirin, Adrenaline, Ancurine, Barbitones, Benzocaine, Chloramphenicol, Sulphathiazole

Safety and Hazards concepts.

Recommended Books:

1) M. G. Larians: Fundametals of Chemicals Engineering Operations
2) W. L. Badger and Banchero: Introduction to chemical engineering (McGraw Hill Servies)
3) L. Lachman – The Theory and Practice of Industrial Pharmacy (Verghesse Publishing)
4) Ganderton G. Unit processes in Pharmacy
5) Groggin P. K. Unit process in Organic synthesis (McGraw Hill Publication London)
6) Marshall Sitting: Organic Chemical Process
7) Dryden C. L. Outline of chemical Technology (Affiliated East-West Press Pvt. Ltd)

10. IMMUNOPHARMACOLOGY AND IMMUNOASSAYS
(3 Hrs/Week)

1) Basic principles:

Cells of the immune system
Non specific immunity
The specific immunologic response antigens and antigen-body binding
Immunoglobulines
The humoral immune response
The cellular immune response
The control of immune response
The complement system

2) Pharmacological aspects of clinical conditions involving immunological mechanism

a) Hypersensitivity
b) Delayed Hypersensitivity
c) Immunomodulators

3) Current concepts in therapy and research of drugs for

a) Acquired immuno deficiency syndrome (AIDS)
b) Tissue transplantation (Immunosuppresants and immunoenhancers)
c) Cancer
d) Vaccines and sera
e) Antifertility drug and vaccine
f) Drug allergy

VI) Methods for (*in-vitro* and *in-vivo*) evaluation of influencing immune system drugs

VII) Biochemical tests used in immunology laboratory

VIII) Radioimmassays (RIA), Enzyme multiplied Immunoassay technique (EMIT)

Fluoroscence polarisation immunoassay (FPIA)
Enzyme linked Immunosorbent Assay (ELISA)
Apoenzme- reactivation immunoassay (NIIA)
Substrate labeled flouroscence immunoassay (SLFIA)
Prosthetic group labeled immunoassay (PGLI)
Immunomodulators of Indigenous origin (plants)

IX) Fc Receptors

Introduction, structure and function of antibodies, conformation of antibodies, Fc8R Family, proteins, transcripts and genes: Gene, Structure and action of high affinity Fc receptor for immunoglobulin E.

Recommended Books:

1) Kirkwood E and Catriona L. Understanding Medical Immunology (john Wiley and Sons, New Yord)
2) Humphrey, J. H. and white R. G. Immunology for students of medicine (Blackwell Scientific Publication London)
3) Goodman and Gilmans. The Pharmacological Basis of Therapeutics (9th Ed.) McGraw Hill 1996

11.TOXICOLOGY
(3 Hrs/Week)

I) Fundamental Principle:

Introduction, toxicological evidence, common household poisons, description of subdisciplines of toxicological, qualitative and quantitative aspects of toxic effects.
Biotransformation: detoxication and bioactivation
Absorption, distribution and elimination of xenobiotics
Toxicokinetics: quantitative aspect
Dose time –effect relationships

II) Molecular aspects of toxicology

Cytotoxicity – molecular mechanism of cell death, genetic toxicology
Introduction to carcinogenesis

III) Organ toxicology

Cytopathology general response patterns and morphological aspects necrosis and apoptosis: Irreversibility of cell damage and cell death.
Dermatotoxicology: Toxicological pathology and methodological aspects
Respiratory toxicology: toxicological pathology methodological aspect.
Respiratory toxicology; pathophysiology, toxicological pathology and mechanisms of toxicity

Gastrointestinal toxicology: toxicological pathology and source of intestinal toxicity
Hepatotoxicological: Mechanisms of liver toxicity and methodology aspects
Nephrotoxicology: toxicological pathology and biochemical toxicology
Cardiovascular toxicology: toxicological pathology and methodology aspects.
Toxicology of blood: Pathophysiology, toxicological pathology and mechanism of toxicity
Immunotoxicology : determination of immunotoxic effects and immunotoxicity mechanism endocrine toxicology
General reproductive toxicology
Functional neurotoxicology
Neurobehavioral toxicology
Food nutritional toxicology
Medical and clinical toxicology
Ecotoxicology
Occupational toxicology
Carcinogenicity mutagenicity: teratogenicity

Recommended Books:

1) Niesink R. J. M. de Vries J and Hollingers M.A. toxicology, Principles and applications, CRC Press 1996
2) Amdur M.O. Doul J. and Klassen C.D. casarettand doull's toxicology
3) Gupta P.K. and salunkhe D.K. Modern toxicology vol – I, II, and III (metropolitan, New Delhi)

12. PHARMACOKINETICS AND THERAPEUTICS DRUG MONITORING (3 Hrs/Week)

1) **a) Introduction to Pharmacokinetics**
   b) Model independent description monoexponential, biexponential and tri exponential dispositions.
   c) Model independent calculation for phamacokientic parameters half life, biological half life, Area under the curve values (from time course equations for c and graphically), Apparent Volumes.
   d) Clearance: Organ Clearance, Total Body clearance, Renal clearance, and renal function tests based on clearance non renal clearance, Hepatic clearance

2) **Compartment models and their limitation** – one compartment open model and multicompartment models. Kinetics of i.v. infusion and multiple dose regimens
3) **Physiological factors related to drug absorption**
4) **Drug distribution and protein binding** – Initial drug distribution drug accumulation drug distribution and pharmacodynamics, protein binding of drugs kinetics of protein binding clinical significance of protein binding

5) **Bioavailability and bioequivalence** definitions relative and absolute availability, methods of assessing bioavailability, bioequivalence studies, clinical significance of bioequivalence studies.
6) **Therapeutic drug monitoring** : introduction, Necessity of TDM Criteria for valid TDM, Essential for effective TDM, organization of a TDM service, information requirements for TDM, effectiveness of TDM
7) Drug selection: Dosage regimen design, Pharmacokinetics of Drug, patient compliance, Evaluation of Pateint's response, Measurement of serum drug concentration, Monitoring serum drug concentration design of dose regimens. Conversion form i.v. infusion to oral dosing. Determination of dose frequently, dosing of drug in elderly.
8) Analytical aspects of TDM, Uses of HPCL and Immunoassays in TDM
9) TDM of selected individual drug – aminoglycosides, carbamazepine, theophylline, digoxin, methotrexate, phenytoin, aspirin, lithium, valproic acid.

Recommended Books:

1) Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and B.C. Andrew
2) Therapeutic Drug Monitoring and Clinical biochemistry by Mike Halworth and Nigel Capps.
3) Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
4) Principle and prescriptive in drug bioavailability by S. Karger
5) Pharmaceutics and pharmacy Pratice by Glibert S. Banker
6) Remington's Pharmacetical Sciences
7) Dissolution, bio-availability and bio-equivalence by Abdou
8) Pharma review by leon shargel
9) Current concepts in pharmaceutical Sciences by James Swarbrick
10) Drug Disposition and Pharmaceutical by Stepphen H. Curry
11) Pharmacokinetics by Milo Gilbaldi and Donald Perrier 2nd Marcle Dekker Inc. New York 19982
12) Drug Level monitoring, Analytical techniques, metabolism and pharmacokinetics
13) Simkin: Handbook of TDM
14) Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.
15) Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974.
16) Clinical pharmacokinetics. Concepts and Applications by Rowland M. and Tozer.T.N 3rd Ed. Lee and Febiger Philadelphia 1995.
17) Pharmacokinetics for pharmaceutical scientist. Wagner J.G. Technomic Inc. Lancaster.P.A. 1993
18) Integration of Pharmacokinetics, Pharmacodynamics and Toxicokinetics in rational drug development. New York 1993
19) Applied Pharmacokinetics, principles of therapeutic drug monitoring by Evans.W.E Schentag J.J and Gusko W.J 3rd Ed. Applied therapeutics Inc. Vancours H.A 1992

13. AGROTECHNOLOGY
(3 Hrs Per Week)

1) **Significance/Importance of Cultivation of medicinal and aromatic plants.** Export potential of medicinal and aromatic plants and their derivatives from India
2) **Cultivation** methods of propagation and factors (exogenous and endogenous) affecting cultivation of medicinal and aromatic plants.
   Endogenous factors Mutation, Polyploidy, chemical races, hybridization etc.
   Exogenous factors Soil – physical and chemical properties, organic matter, micro organism of soil, soil classification and soil management, soil testing. Influence of altitude, temperature, humidity, rainfall/irrigation.
   Soil fertility and fertilizers – plant nutrition and their functions, maintenance of soil fertility, types of manure and fertilizers, mode and time of application of fertilizer and manure.
   Weeds and Weed Control – disease and pest of medicinal and aromatic crops and their control
3) **Agro products Marketing and Storage**
4) **Methodology for assessment of availability of medicinal and aromatic plants materials from the forest.**
5) **Scientific study of cultivation, collection and preparation for market of followings, along with their products and byproducts.**
   a) Dioscorea
   b) Senna
   c) Isapgol
   d) Neem
   e) Mentha
   f) Solanum
   g) Jasmine
   h) Spirulina

6) **Study of following Agro based products:**
   a) Starch and its derivatives
   b) Cellulose and its derivatives
   c) Activated Carbon
   d) Catechu and Catechin
   e) Alginate and its derivates
   f) Plant products for insect control
   g) Cheese, butter, yoghurt from milk

7) **Sericulture(Silk Production) – Technique and prospects**

Recommended Books :

1) Wealth of India : CSIR New Delhi
2) A handbook of agriculture – ICAR New Delhi
3) Cultivation and Utilization of medicinal plants, C.K. Atal and B.M. Kapoor RRL, CSIR
4) Cultivation and Utilization of Aromatic plants, C.K. Atal and B.M. Kapoor RRL, CSIR

5) Spices, Plantation crops, medicinal and aromatic plants. N.Kapoor, J.B.M.Md. Abdul Khader, P. Rangaswamy, I. Irulapan – Oxford and IBH Publishing Company Pvt. Ltd. New Delhi
6) Materia Medica : Nadkarni, Kothari

14. PHARMACEUTICAL MARKETING
(3 Hrs/Weeks)

1) Concept of Pharmaceutical Marketing, selling and Organisation structure:

1) Meaning of pharmaceutical marketing and selling
2) Organisation structure of pharmaceutical marketing dept. Job responsibilities of people involved.
3) Customers in Pharmaceutical marketing

2) Advertising and Sales Promotion in Pharmaceutical Marketing:

1) Advertising of Pharma products and Detailing concepts.
2) Various sales promotion Methods its advantages and disadvantages
3) Medical representative and his role
4) Various strategies to sell pharmaceutical products

) Distributor and Retailer in Pharma. Business

1) Retailer and his importance
2) Distributor and his importance
3) Retail prescription audit

Institutional Business :

1) Types of institutions
2) Promotion activities at institutions
3) Advantages of Institutional Business

nternational Pharma Marketing Management:

1) International Pharma Market
2) Export management of pharmaceuticals

ommended Books :

1) Pharmaceutical marketing by Subba Rao
2) The Fast Track Career. M.R.S.S. Nadkarni

15 PHARMACEUTICAL ADMINISTRATION
(3 Hrs/Week)

1) Introduction to Pharmacy Administration

1) Concepts, Nature and Purpose of management – Differentiation between Administration, Management and Organisation
2) Pharmaceutical management : An art, science or profession
3) Social responsibilities of management and functions of management

2) Planning and decision making in pharmaceuticals

1) Planning Purpose and nature and its use in pharmaceuticals
2) Types of planning and standard operating procedures in planning
3) MBO Process and its applicability in pharma marketing
4) Strategies in pharma marketing, policy, procedure and methods in pharma production
5) Decision making, process and problems

3) Pharmaceutical organization and organizing

1) Organisation structure of pharmaceutical industry
2) Authority and delegation and its applicability
3) Line and staff organization concepts

4) Human Resource Management in Pharmaceuticals

1) Manpower planning and recruitment and selection
2) Various types of training and development in pharmaceutical industry
3) Performance appraisal
4) Directing, Leadership styles, theories of motivation, incentives
5) Communication skills and its importance in pharmaceuticals

5) Various controls in Pharmaceutical Industry

1) Importance of various controls
2) Budgetary control, Non-budgetary controls in pharmaceuticals
3) Controlling overall performance of pharmacy industry

6) Techniques and models for improving pharma performance

1) Break even analysis and its application in pharmaceutical industry
2) PERT – CPM method and its application to pharma business
3) Inventory management models useful in pharmaceutical industry

Recommended Books

1) Management, tasks, responsibilities and practices by Peter Drucker 1881. Alfied Publishers Pvt. LTd.
2) Personnel management by C.B. Momoria, Himalaya Publishing House 1992

16. MEDICINAL PLANT BIOTECHNOLOGY
(3 Hrs/Week)

1) Introduction to plant genetic structure and molecular biology.
2) Plant gene mapping and molecular maps of plant genomes
3) Methods of quality improvement of plants
   a) Chemodemes
   b) Hybridization
   c) Mutation
   d) Polyploidy

4) Gene transfer in plants
   a) Using vectors of Agrobacterium Ti, co-integrative, Intermediate plasmid
   b) DNA mediated gene transfer
   Electroporation, microprojectiles, micro and macro injection, liposomes, utrasonication
5) Localisation of transferred gene in genetically modified plants
   a) Plant chromosome analysis
   b) Gene mapping
   c) Use of markers
   d) DNA hybridization
6) Application of transgenic plants
   a) Resistance of herbicides, insect, fungus and viruses, physiological stress
   b) Edible vaccines
7) Plant tissue culture
   a) Totipotency
   b) Culture media
   c) Types of culture
   d) Cell suspension, organogenesis, embryogenesis, protoplast culture
   e) Cell immobilization
   f) Bio-transformation
   g) Generation and production of secondary metabolites
   h) Germ plasma conservation

Recommended Books

1) Element of Biotechnology by P. K. Gupta
2) Molecular Biology and Biotechnology. J. M. Walker, E.D. Gingo
3) Essentials of Molecular Biology. David F. A, George.M.M
4) An Introduction to plant tissue culture. M. A. Razdan.
5) Plant Biotechnology – Samtel
6) Plant tissue culture. Narayanswamy Tata McGraw Hill
7) Plant tissue culture. Angela Stafford, Open University Press, Buckingham 1991
8) Plant tissue culture – Dixon
9) Pharmaceutical biotechnology – Vyas, Dixit, CBS publisher 1998
10) Pharmacognosy – Trease, Evans 15th Ed.

17. PHYTOPHARMACEUTICALS
(3 Hrs/Week)

Source, Phytochemistry (Isolation, identification, chemical nature), and physiological activities of following phytopharmaceuticals

1) **Anticancer** – Taxol, other taxanes, camptothecin,vinblastine, genticin, etoposide
2) **Nervous Sytem Activities** – Hypericin, valepotrictes, gingkolides
3) **CVS Activities** – Colenol, streptokinase
4) **Antiinflammatory** – Curcuminoids, guggulipids, boswellic acids, serratopeptidase

5) **Miscellaneous** – Silymarine, artemisinin, omega 3-fatty acid Charantin and Momordiscosides, resveretrol, protamine sulphate, prostaglandins

Recommended Books

1) Pharmacognosy – Trease, Evans 15th Ed.
2) Pharmacognosy – Gokhale,Kokate, Purohit
3) .Bio chemistry – Delvin
4) Alkoloids. Edited by J.R.F. Manske
5) Various research journals on Natural Products and Therapeutics

18. DRUG DESIGN
(3 Hrs/Weeks)

1) Drug Discovery -

1) Historical perspective
2) Drug Discovery Strategies in Direct Drug Design (Structure based) and indirect drug design.
3) Target selection and lead Identification.
   a) Natural product sources
   b) Fermentation/Microbial sources
   c) Synthetic

2) QSAR -

a) Parameters – Lipophilicity, electronic, steric factors
b) Quantitative Models-
   i) Hansch analysis ii) Free Wilson Analysis iii) Mixed approach
c) Other QSAR Approaches
d) Applications of Hansch Analysis, Free Wilson Analysis.

3) ENZYMES. PEPTIDES IN DRUG DESIGN

4) MOLECULAR MODELING IN DRUG DESIGN
1) Introduction to Molecular Modeling: Concepts and Methods
a) Molecular Mechanics – force fields (Potential energy function)
b) Energy Minimisation Methods – Steepest, descent, Conjugate gradients, Newton methods. (Non mathematical)
c) Conformational Analysis
i) Systematic search
ii) Monte carlo simulations
iii) Molecular dynamic simulations
d) Ligand design based on 3D structure of receptor/enzyme

RECOMMENDED BOOKS:

1) Hugo Kubingi – QSAR, Hansch Analysis and Related approaches Vol. 1
2) Poul Krogsgaand Larsen: A text books of Drug Design and Development First Edi.
3) Thomas J. Perum, C L. Propst – Computer Aided Drug Design
4) Pandi Veerapandian – Structure Based Drug design
5) Paul S. Charifson – Practical Applications of Computer Aided Drug Design (Marcel & Dekker Inc. New York)
6) Paul Leff – Receptor Based Drug Design
7) Bernard Testa, Walter Fuhrer – Perspectives in Medicinal Chemistry
8) C. Hansch Comprehensive Medicinal Chemistry Vol. IV

19. HERBAL DRUG TECHNOLOGY
(3 Hrs/Week)

1) **Plant Extracts, Preparation and standardization**
Withania somnifera, Tinospora cardifolia,, Curcuma longa, Solanum xathocarpum, Ocimum sanctum, Tribulus terrestris, Adhatoda vasica, Emblica officinalis, Centella asiatica, Melia azadirachta.
2) **Traditional drug formulations**
   i) Ayurvedic (Asava, Arishta, Bhasma, Kwatha, Ghruta, Avaleha)
   ii) Homoeophathy
   iii) Siddha
   iv) Unani (Sarbat, Saffoof, Mazoon, Jawarish, Laooq)
   v) Aromatherapy
3) **Herbal drug formulations** (Various biological and drug aspects)
   i) Therapeutic drugs used
   ii) Cosmetics: Skin, Hair
4) **Agroproducts of economic significance** Cornoil, Soybean, Spirulina, pectin, papain.
5) **Standardization of phytopharmaceuticals** by HPTLC technique Bacoside, Andrographolide, Solasodine, Kutkoside, Lupeol.
6) **Standardisantion of phytopharmaceuticals** by HPTLC technique Bacodise, Andrographolide, Solasodine, Glycerrhetinic acid, Vasicine, Sennosides.

Recommended Books: (For Advanced Pharmacognosy I, II & III Theory)

1) Herbal Drug Industry: R. D. Chaudhary, Eastern publishers, New Delhi 1996
2) Wealth of India, CSIR New Delhi (Related Vol)
3) Cultivation & Utilization of medicinal plants: Atal & Kapoor, RRL Jammu
4) Cultivation & Utilization of aromatic plants: Atal & Kapoor, RRL Jammu
5) Various journals related to medicinal plants
6) Pharmacognosy: Trease W.C. Evans G. E. Bailliere & Tindall, London, 14th edtn.
7) Britisb Herbal Pharmacopoeia: (Vol I,II, III) Her Majesty's Sevrices, U.K.
8) Ayurvedic formulary of India, Govt. of India 1962
9) HPLC methods of drug analysis: Mantu K. Ghosh
10) Phytochemical methods : J. B. Harborne
11) Variouse Research Journals on Medicinal natural products.
12) Pharmacognosy : Kokate, Purohit, Gokhale, 15th edition, Nirali Prakashan, Pune

20. ADVANCED PHARMACEUTICS-I (THEORY)

Theory (3hrs/week)

Preformulation Studies: on various dosage forms such as tablets, capsules, suspension, creams, emulsion, injectables, opthalamichs, and aerosols etc.

Advances in Solid dosages forms: Physics of tables compression, direct compression, recent advances in tablet coating, microen capsulation and uses of newer encapsulating agents and techniques. Particle size enlargement – various methods and application.

Advances in liquid dosages forms: Theoretical and particle aspects in the manufacture of liquid dosage forms such as suspension, emulsion.

Solublization, formulation of parenteral suspension and emulsion. Techniques and principles involed in the formulation of multiphase and microemulsion. Mechanism of droplet stabilization. Stability of multiphase and microemulsion. Destablilization kinetics.

Parentarl dosage forms: Processing of small and large volume parenterl raw materials, principle and technique. Stability evaluation environment, personnel and management factors in control and quality assurance.

Stability studies and kinetics: stability and stabilization of Pharmaceuticals, Stability calculation, rate equation, activation energy calculation, interpretation of kinetic data, stability data in product development. Accelerated stability testing. Factors to responsible for destabilization of pharmaceutical product and techniques and means to improve stability. Mathematical treatment of stability test data. Calculation shelf life, Calculation of Q. 10 value and application Q. 10 value in stability testing.

Production management: Organization structure, objectives and polices, good manufacturing practices, layout of buildings, service, equipments and maintenance – detail discussion. Material management handling and transportation, production planning and control, industrial relations. Safety laws related to production and licensing factories act.

Packaging Technology: Role of packaging in protecting product. Packaging materials such as glass, plastics, metals, and paper based material, ancillary materials use in packaging materials, economics of packaging methods and packages. Safety consideration and law relating to packaging.

Polymer Sciences: Pharmaceutical applications of polymer, properties of polymers. Thermodynamics of polymer solution, phase separation, coacervation and microencapsulation. Polymer in solid state.

Books Recommended:

1) Remington's Pharmaceutical application of polymers, properties of polymers. Thermodynamics of polymer solution, phase separation, coacervation and microencapsulation. Polymer in solid state.

2) Theory and practice of Industrial Pharmacy Leon Lachman. Herbert A Lieberman and Joseph L. kaning. Varghese Publishing House, Bombay

3) Essential of Physical Chemistry and pharmacy Arnikar, Kadam, Gujar, Orient Longman.

4) Quality Control in The pharmaceutical Industry: Volumes 1,2 and 3, Murrary

5) S. Copper Academic Press, New York and academic Press London.

6) Good Manufacturing Practices for pharmaceuticals – A plan for total Quality Control. S. H. Willing, M. M. Tuckerman, S. Hitchings, Marcel Dekker, Inc. New York.

7) Pharmaceutical Preformulation by J. I. Wells, John wiley & sons, N.Y.

8) Chemical Stability of Pharmaceutics – A Handbook for Pharmacists – Kenneth A Connors, Gordon L. Amidon. Voluation J. Stelle, John Wiley & Sons, New York.

9) Pharmaceutical Dosage Forms: Parenteral Medications Volumes 1, 2 and 3. Kenneth E. Vavis, Loan Lachman and Herbert A. Lichman. Marcel Dokker New York.

10) Pharmaceutical Dosage Forms: Dispersed System Vol. 1 & 2 Edited by as 13.

11) Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.

12) Sterile Dosage Forms, Salvatore Turbo and Rebest E. King Lea and Febiger, Philadelphia.

13) Pharmaceutics – The Sciences of Dosage Form Design Michael E. Aulton, Churchill Livingstone, New York.

14) Advances in Pharmaceutical Sciences, Edited by Bean, Bockett and Carless, Academic Press, New York.

15) Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.

16) Physical Pharmacy: A. N. Martine, James Swarbrick and Commarate (Lea & Febiger, Philadelphia)