ADMISSION & EXAMINATION RULES

Master of Pharmacy

(Approved by the Academic Council in 2002, to be effective from the Academic Session 2002-2003 and applicable to all M. Pharm students)

Programme : Master of Pharmacy (M. Pharm) in the following subjects.

- i) Pharmaceutical Chemistry
- ii) Pharmaceutics
- iii) Pharmacognosy & Phytochemistry
- iv) Pharmacology
- v) Quality Assurance
- vi) Pharmacy Practice

It shall be a full time regular course.

During an academic year, a candidate shall be enrolled only for one programme of study and shall not appear in any other examination of this or any other University.

Duration : Four semester which will be designated as under :

- Ist Semester - July-Dec.
- IInd Semester - Jan-June
- IIIrd Semester - July-Dec.
- IVth Semester - Jan-June

Medium of instruction and examination : English

Eligibility of admission : A candidate seeking admission to M. Pharm course must have :

- Passed Bachelor of Pharmacy from Jamia Hamdard or any other examination recognized by Jamia Hamdard as equivalent there to, with at least 55% marks or above in aggregate of theory marks of B. Pharm I, II, III & IV year.

For admission to M. Pham programme, the merit of GATE qualified candidates will be determined on the basis of the following criteria :

- i) Weightage for percentile scored at GATE…….70%
- ii) Written test 30%

For the Non – GATE candidates, the selection of candidates will be made on merit based on the aggregate marks of theory papers of I, II, III and IV years of B. Pharm. Examination or any other examination recognized by Jamia Hamdard as equivalent there to. Further, the admission of Non – GATE qualified candidates to a particular specialization will depend on the availability of seats in the respective specialization after the selection of the GATE qualified candidates.

Completed the age of 20 years on or before the first day of October of the year of admission.

Course Structure : The course work shall be divided into four semesters. The course contents are given in the Syllabus

Scheme of Examination :

Scheme of examination for M. Pharm in :

- (i) Pharmaceutical Chemistry
- (ii) Pharmaceutics
- (iii) Pharmacognosy & Phytochemistry
- (iv) Pharmacology
- (v) Quality Assurance

Modern Analytical Techniques theory and Practical mentioned under section A shall be common for the M. Pharm Course in the following branches

- i) Pharmaceutical Chemistry
- ii) Pharmaceutics
- iii) Pharmacognosy & Phytochemistry
- iv) Pharmacology
- v) Quality Assurance

Section – A				
Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks
I	Modern Pharmaceutical Analytical Techniques	I Theory	3	100
I	Modern Analytical Techniques	I Practical	6	100
Section – B				

Branch I. Pharmaceutical Chemistry				
Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks
I	Pharmaceutical Chem. – I (Drug Design including Organic name reactions)	II Theory	3	100
II	Pharmaceutical Chemistry-II (Chemistry of Natural Products)	III Practical	3	100
II	Pharmaceutical Chemistry-III (Medicinal chemistry)	IV Theory	3	100
II	Pharmaceutical Chemistry Pract.	I Practical	12	100
III	Pharmaceutical Chemistry Pract.	II Practical	12	100
Research Project work synopsis/Seminar				
IV	Thesis			300
	Viva Voce			200
				Total 1200

Branch – II Pharmaceutics				
Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks
I	Pharmaceutics – I (Product Development and Quality Assurance)	II Theory	3	100
II	Pharmaceutics – II (Industrial Pharmacy and Packaging Technology)	III Theory	3	100
II	Pharmaceutics – III (Advances in Drug Delivery Systems)	IV Theory	3	100
II	Pharmaceutics Pract. I	Practical	12	100
III	Pharmaceutics Pract. II (Research Project work Synopsis/Seminar)	Practical	12	100
IV	Thesis			300
	Viva Voce			200
				Total 1200

Branch – III Pharmacognosy and Phytochemistry				
Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks
I	Pharmacognosy andPhytochemisty – I (Advances in Pharmacognosy)	II Theory	3	100
II	Pharmacognosy andPhytochemistry – II (Phytochemistry and Biogenesis)	III Theory	3	100
II	Pharmacognosy andPhytochemistry – III (Cultivation & Standardi-sation of Medicinal Plants)	IV Theory	3	100
II	Pharmacog. & Phytochem. Pract.	IPractical	12	100
III	Pharmacog. & Phytochem. Pract. II Practical(Research Project work Synopsis/Seminar)	Practical	12	100
IV	Thesis			300
	Viva Voce			200
				Total 1200

Branch IV. Pharmacology				
Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks
I	Pharmacology-I (Basic Principles of Drug Therapy & Clinical Pharmacology)	II Theory	3	100
II	Pharmacology – II (Recent Advances & Emerging Trends in Pharmacological Sciences)	III Theory	3	100
II	Pharmacology – III(Pharmacological Methods and Toxicology)	IV Theory	3	100
II	Pharmacology Pract. I	IPractical	12	100
III	Pharmacology Pract. II	Practical	12	100
IV	Thesis			300
	Viva Voce			200
				Total 1200

Branch V. Quality Assurance				
Semester	Name of the Subject	Paper No.	Duration Of	Total

I	Quality Assurance-I (Product Development)	II Theory	3	100
II	Quality Assurnace-II (Packaging)	III Theory	3	100
II	Quality Assurance-III(Biological Evaluations and Validations)	IV Theory	3	100
II	Quality Assurance-I (Practicals)	IPractical	12	100
III	Practical II (Synopsis of Project work Seminar)	Practical	12	100
IV	Thesis			300
	Viva Voce			200
				Total 1200

The Thesis work can be completed in Jamia Hamdard or else in a Pharmaceutical Industry/ R&D Laboratory / Analytical Testing House/National Laboratory, and in which case a co supervisor would be from such relevant institution.

6 B. Scheme of examination (For M. Pharm in Pharmacy Practice)

Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks
I	Pharmacotherapeutics (Including Pathophysiology)	I Theory	3	100
I	Basic Principles of Clinical Pharmacy	II Theory	3	100
II	Pharmacotherapeutics Clinical Practical (Including Pathophysiology)	Practical I	6	100
				Total 300

Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks
II	Hospital and Community	III Theory	3	100
II	Drug Toxicity and Management of Drug Information Service	II Theory	3	100
II	Preparation of Clinical Manual for the treatment of various disorders	Practical II	12	100
				Total 300

Semester	Name of the Subject	Paper No.	Duration Of Exam	Total Marks

III	Synopsis of Project work	III Theory	12	25
III	Seminar	III Theory	12	25
II	Clinical Practical	Practical II	12	50
				Total 100

Semester	Name of the Subject	Duration Of Exam	Total Marks
IV	Thesis	300	
IV	Viva- voce	200	
			Grand Total 1200

The thesis work will be done in the Majeedia Hospital under the supervision of clinical Pharmacist and clinician.

Course Structure in four Semesters

There will be at least 90 working days in each Semester. The distribution of subjects will be as follows.

Course Structure in four semester for M. Pharm in
(I) Pharmaceutical Chemistry

(ii) Pharmaceutics

(iii) Pharmacognosy & Phytochemistry

(iv) Pharmacology

(v) Quality Assurance

Semester – I

Modern Analytical Technique

(This paper is Common in first Semester of all Branches except Pharmacy Practice)

Paper – I Modern Analytical Technique

Modern Analytical Technique	Theory	4 Hours / Week
Modern Analytical Technique	Practical	12 Hours / Week

Branch – I Pharm. Chemistry

Branch – I Pharm. Chemistry

Pharm Chemistry – I*#	Theory	4 Hours / Week

Branch- II Pharmaceutics

Paper – II		
Pharmaceutics – I*#	Theory	4 Hours / Week

Branch III Pharmacognosy

Paper – II		
Pharmacognosy & Phytochemistry (Advances in Pharmacognosy)*#	Theory	4 Hours / Week

Branch IV (Pharmacology)

Paper – II		
Pharmacology – I(Basic Principles of Drug Therapy & Clinical Pharmacology)*#	Theory	4 Hours / Week

Branch V (Quality Assurance)

Paper-II		
Quality Assurance-I*#	Theory	4 Hours / Week

*Practical in the respective Specialization	4 Hours / Week
#Seminar / Tutorials and Journal Club	12 Hours / Week

At the end of Ist Semester following examination will be held as per the scheme of examination

Modern Analytical Technique	Theory
Modern Analytical Technique	Practical
Paper – II of Respective Specialization.	Theory

Semester – II

Branch – I

Pharm. Chem.	II (Paper III)	Theory	4 Hours/Week
Pharm. Chem.	III (Paper IV)	Theory	4 Hours/Week
Pharmaceutical Chem. Pract. IPractical II		Practical	18 Hours/Week

Branch – II

Pharmaceutics	II (Paper III)	Theory	4 Hours/Week
Pharmaceutics	III (Paper IV)	Theory	4 Hours/Week
Pharmaceutics Pract. I		Practical	18 Hours / Week

Branch – III

Pharmacognosy	II (Paper III)	Theory	4 Hours/Week
Pharmacognosy	III (Paper IV)	Theory	4 Hours / Week
Pharmacognosy Pract. I		Practical	18 Hours/Week

Branch – IV

Pharmacology	II (Paper III)	Theory	4 Hours/Week
Pharmacology	III (Paper IV)	Theory	4 Hours / Week
Pharmacology Pract. I		Practical	18 Hours/Week

Branch-V

Quality Assurance-II	Paper III	Theory	4 Hours/Week
Quality Assurance-III	Paper IV	Theory	4 Hours / Week
Quality Assurance Pract. I		Practical	18 Hours/Week

*--Seminar / Tutorials/ Journals Club/ Group Discussion -- 14 Hours / Week
(For all branches in respective specialization)

At the end of **IInd Semester** the examination of following subjects will be held as per the scheme of examination.

- Paper III Theory}
- Paper IV Theory} of respective Specialization's
- Practical I Practical} of respective specialization

IIIrd Semester

Practical II of the respective specialization related to research work will be conducted in the third semester and carry 50 marks. The synopsis, seminar and corresponding viva of the research envisaged will carry 50 marks. (Total 100 Marks). The above examination will be held by a Committee Consisting of HOD, one external examiner and the respective supervisors for two days duration and submit the marks awarded to the controller of examination.

- Practical II of Respective specialization 12 Hours/ Week
- Research Project work 28 Hours/ Week

IVth Semester

Fourth Semester will be entirely devoted to the research project. The examinations shall consist of a thesis and Viva- Voce. The Weightage of marks for the thesis and Viva Voce shall be as under

- Thesis - 300 marks
- Viva Voce - 200 marks

Course structure in four semester for M. Pharm in Pharmacy Practice

Semester-I

Pharmacotherapeutics(Including Pathophysiology)	Paper I	Theory	4 Hrs./Week
Basic Principles of Clinical Pharmacy	Paper II	Theory	4 Hrs./ Week
PharmacotherapeuticsClinical Pratical-I (Including Pathophysiology)		Practical	30 Hrs./Week

At the end of Ist Semester following examination will be held as per the scheme of exmination.

Pharmacotherapeutic (Including Pathophysiology)	Paper I	Theory	3 Hrs
Basic Principles of Clinical Pharmacy	Paper II	Theory	3 Hrs
Pharmacotherapeutics Clinical Pratical-I (Including Pathophysiology)		Practical	6 Hrs.

Semester-II

Hospital and community Pharmacy	Paper III	Theory	4 Hrs./Week
Drug Toxicity and Management of Drug Information Services	Paper IV	Theory	4 Hrs./Week
Preparations of clinical manual forThe treatment of various disorder Research Project & Synopsis	Practical II	Practical	30 Hrs./Week
Seminar tutorial		2 Hrs./Week	

At the end of IInd semester the examination of following subject will be held as per the scheme of examination

Hospital and community Pharmacy	Paper III	3 Hrs
Drug Toxicity and Management of Drug Information Services	Paper IV	3 Hrs
Preparations of clinical manual for The treatment of various disorder (In the Hospital)	Practical II	12 Hrs.

Semester-III

In addition to practical II, the third semester will be mostly devoted to the research project.

Preparation of clinical manual for the treatment of various disorders	Practical II	12 Hrs./Week
Pharmacotherapeutics Clinical Pratical-I (Including Pathophysiology)		28 Hrs./Week

Semester-IV

Fourth Semester will be entirely devoted to the research project. The examinations shall consist of a thesis and viva voce. The weightage of marks for the thesis and viva voce shall be as under

- **Thesis :** 300 Marks
- **Viva Voce :** 200 Marks

Attendance

a) All Students must attend every lecture and practical class However, to account for late joining or other such contingencies, the attendance requirement for appearing the examinations shall be a minimum of 75% of the classes actually held.

b) In order to maintain the attendance record of a particular course, a roll call will be taken by the teacher in every scheduled lecture and practical class. For the purpose of attendance, every scheduled practical class will count as on attendance unit, irrespective of the number of contact hours.

c) The teacher incharge will consolidate the attendance record for the lectures and practical for each term. Attendance on account of participation in the prescribed functions

of NCC, NSS, Inter University sports, educational tours / field work record, duly countersigned by the Officer Incharge, is sent to the Dean of Faculty within two weeks of the function / activity, etc.

d) The statement of attendance of students shall be displayed on the department Notice Board at the beginning of very month of university calendar. A copy of the same shall be sent to the Head of Department / office of Dean of Faculty for record. Notice Displayed on Notice Board shall deemed to be a proper Notification, and no individual notice shall be sent to students.

e) If a student is found to be continuously absent from the classes without information for a period of 30 days, the teacher incharge shall report it to the Head Of Department / Dean for striking off the name of such student from rolls. Such a Student may, however, apply, for readmission within 15 days from the date of issue of the notice of striking off the name. The request may be considered by the Dean for re-admission. Such a student shall not be readmitted after the prescribed period. The re-admission shall be effected on payment of prescribed readmission fees.

f) A student with less than 75% attendance of the lectures and practical separately in each subject / course in a semester shall be detained from appearing in the university semester examination. The Dean of Faculty concerned may consider application for the condonation of attendance upto 5% on account of sickness, provided the application for condonation of attendance on account of illness, duly certified by a Registered Medical Practitioner / Public Hospital had been submitted within 5 days from the recovery from illness. Condonation of attendance on account of any other extenuating circumstances is by documentary evidence.

g) A student detained on account of attendance will be re-admitted to the same class in the next academic year on payment of current fees except enrollment fee, Identity Card fee and Security deposits.

Semester Examination

a) Semester examination shall be held as per schedule given in the Academic Calendar of Jamia Hamdard. There shall be no supplementary examination. Candidates shall appear in the examination of their uncleared courses at the next semester examination of the same course along with other students of junior batch. Thus the left over courses of first semester shall be cleared in the IIIrd semester and those of IInd semester in IVth semester Like-wise, leftover courses of III and IV semester would be taken by the student next year along with the junior batch.

b) The practical examination shall be conducted by an external examiner but two internal examiners instead of one may be appointed to conduct the practical examination, if it becomes necessary in view the nature of practical exercises.

c) The question papers shall be set by an external examiner.

d) The subject of thesis shall be approved on the recommendations of the Supervisor and the Head of Department. One or more than one supervisor may be appointed in a particular case.

e) A candidate shall not be entitled to submit the thesis unless he/she has pursued his/ her research during 3rd and 4th semester under the guidance of supervisor (s). The thesis shall embody the result of the applicant's own research. It shall indicate in what respect his / her contribution appears to advance, the knowledge of subject. The final results of the candidates will be declared only when he / she passed all examinations of Semester I, Semester II and Semester III.

f) Every candidate shall submit three printed or typed hard bound copies of his / her thesis, through the Supervisor and Head of Department, normally by the end of Aug. of the year of submission. However, an extension for submission of thesis may be granted upto 30 Sept. of the year upon the request of the student duly recommended by the supervisor. On receipt of thesis, the University shall appoint two examiners, One external and one Internal, to examine the thesis and conduct the Viva Voce.

g) The examiners shall jointly assess the thesis and award marks for the thesis and Viva-Voce. In case, the candidate fails to secure the minimum pass marks on the combined performance of the thesis and viva voce, he / she may be asked to revise the thesis in the light of the suggestions of Examiners or submit a fresh thesis on his / her being enrolled as an ex-student in relation to the next semester examination. A re-submitted, thesis will be examined by the same examiner unless they are unable or unwilling to act as Examiners. Resubmission of the thesis, shall be permitted, after the candidates has put in three months of research work and resubmit the same within six months from the date of publication of result in the first instance and after at least six months of the research work when the thesis is rejected subsequently.

h) The minimum pass marks shall be 50% in each theory / Lab course / thesis and Viva Voce (Combined), as also in aggregate of the semester.

Promotion

A candidate who fails to secure 75% attendance in any course during a particular semester will have to seek re-admission

A student shall be promoted to the next semester of the programme if he / she has passed in each of theory and practical separately. However, a student may carry over a maximum of one paper or practical to the next semester. Such candidate who fails in more than one paper shall seek re-admission in Ist semester in the next academic session as regular student. No candidate shall be promoted to M. Pharm semester IV if he/she fails in more than two courses of the proceeding three semester taken together such student shall seek re-admission in IIIrd semester in the next academic session as a regular student. After the declaration of the IVth semester results if a candidate fails in any Theory/Practical taking all the four semester together he/she will have to re appear in these courses in concerned semester in next academic year as an ex-student along with the next batch.

Classification of Successful Candidates

(a) The result of the successful candidates shall be classified at the end of 4th examination on the basis of the aggregate of all subjects. Theory and Practical secured by the candidate in the I, II, III and IV semester exams indicated below.

Ist Division 60% & above

IInd Division 50%-59.9%

(b) Candidates securing 75% or above marks in any course (s) and have passed whole of the examination in first attempt shall be declared to have obtained Distinction in that course (s).

(c) A Student shall be eligible for award of Gold Medal subject to the following criteria :

(i) He (She) has secured the highest marks in aggregate of four semesters of the programme of study.

(ii) He (She) has passed all examinations, including qualifying courses, if any, in first attempt.

Span Period

(a) Students admitted to M. Pharm course must pass the Ist Semester examination within 24 months from the Ist admission to the course.

(b) Student must complete all the requirement of M. Pharm degree within a total period of five years from their admission.

Other Conditions

The Non-GATE qualified candidates admitted to this Programme will be required to deposit with Jamia Hamdard an amount equivalent to the contingency grant given by UGC to GATE qualified candidates.

Syllabi

Syllabus For M. Pharm

in

Pharmaceutical Chemistry

(Including the Syllabus of Modern Analytical Techniques {Theory & Practical} common in the Ist Semester of all Branches of M. Pharm expect M. Pharm in Pharmacy Practice)

Effective from Session

2002-2003

This Paper (Theory & Practical) is common in Ist semester of all Branches of M. Pharm except
M. Pharm in Pharmacy Practice

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

Infrared spectroscopy

Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

Ultraviolet spectroscopy :

Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore s ® s*, h®s*,p® p*, h® p*, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

Nuclear Magnetic Resonance spectroscopy :

A. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

B. 13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

Mass Spectrometry:

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

Thermal analysis:

Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

Pharmacological evaluation of drugs in biological fluids: Bioassay.

Microbiological assays.

Radioimmunoassays.

Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index,palisade ratio, vein-islet number, and vein-termination number.

BIOSTATISTICS AND COMPUTER APPLICATION

1. Methods of collection of data, classification of data, graphical representation of data, frequency, polygon, histogram, measure of central tendency, mean mode and median dispersion and standard deviation.

2. Confidence level, Null hypothesis, calculation of statistical significance between two means, analysis of variance.

3. Association of attributes centigency, classification of attributes, coefficient of association, chi square test.

4. Theory of probability, simple probability, law of probability, Permutation and combinations, ratios percentages and proportions and statistical difference between proportions. Analysis of variance two way ANOVA and multiple comparison procedures.

5. Correlation and regression, least square method and its application, significance of coefficient of correlation, non linear regression.

6. Calculation of ED50, LD50, probit analysis.

II COMPUTER APPLICATIONS

BOOK RECOMMENDED

1. R.M.Silverstein, F.X.Webster, Spectrometric Identification of organic compounds, 6th ed. John Wiley & sons, New-York, 1998.

2. Remington, The science and practice of pharmacy, Mack publishing company. Easton Pennsylvania.

3. Organic spectroscopy by Willam Kemp

4. E. Heftmann, A laboratory handbook of chromatography, New - York.

5. H.H.Willard, L.L.Merritt and J.A.Dean, Instrumental methods of analysis, Van Nostrend Reinhold, New York.

6. WWM. Wenland, Thermal analysis, John Willy and sons, New-York.

7. Principle of instrumental analysis,V ed. By Skoog, Holler-Niemen.

8. Modern analytical chemistry by David Harvey. (MC Graw-Hill international edition).

PRACTICALS

Practicals based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.

Modern Pharmaceutical Analytical Techniques (Theory & Practical) is a common subject

in the first semester of the first five branches of Master of Pharmacy

Semester No. I No. of Teaching Hrs. 4 Hrs / Week

Paper II Duration of Exam 3 Hrs.

Max. Marks. 100

PHARMACEUTICAL CHEMISTRY – I DRUG DESIGN INCLUDING ORGANIC NAME REACTIONS

1. Physicochemical properties in relation to drug action; metabolic transformation of drugs and its role in development of new drug molecules; Metabolic antagonism.

2. Stereochemical aspects of drug receptor interactions and mechanism of drug interaction. Isosterism and bioisosterism as guides to structural variations; Concepts of conformational analysis and its role in design and development of new drug molecules.

3. Principle of drug design: Analogue synthesis versus rational design; discovery of lead compounds, Pharmacophoric identification, Prodrugs and soft drug.

4. QSAR and introduction to molecular modeling.

5. In organic chemistry, the following name reactions and molecular rearrangements will be discussed in detail with reference to their application in the synthesis of some medicinal agents, where possible.

(a) Claisen- Schmidt reaction e.g. Sulfisoxazole.

(b) Perkins reaction e.g. sulinadac

(c) Friedal Craft Reaction

(d) Aldol condensation

(e) Mannich reactions e.g. Tolmetin, Atropine, Ethacrynic acid, Dextropropoxyphen.

(f) Beckmann's rearrangement.

(g) Wagner-Meerwein rearrangement

(h) Wittig Reaction

(i) Oppenaur oxidation.

(j) (Meervein- pondroff-verley) M.P.V. Reduction.

BOOKS RECOMMENDED

1. E.J. Ariens : Drug Design, Academic Press New York (1975).

2. S.H. Salkovisky. A.A. Sinkula and S.C. Valvani, Physical Chemical Properties of Drug, Marcel Dekker Inc. New York.

3. M.E. Wolff, Burger's Medical Chemistry, John Willey and Sons. New York.

4. R.F. Doerge, Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, J.Lippincott Co., Philadelphia.

5. J. March, Advanced Organic Chemistry, Reaction Mechanism and Structure, John Wiley and Sons, New York.

6. E.S. Gould, Mechanism and Structure in Organic Chemistry Holt, Rinewart and Winston, New York.

Semester No. 2 No. of Teaching Hrs. 4 Hrs / Week

Paper III Duration of Exam 3 Hrs.

Max. Marks. 100

PHARMACEUTICAL CHEMISTRY-II CHEMISTRY OF NATURAL PRODUCTS

1. **Natural products as Leads for new pharmaceutical.**

2. The natural products obtained from terrestrial and microbial sources will be discussed in the light of various degradative and synthetic approaches supported by spectral data. Important members representing the following classes of natural products shall be discussed.

2.1 **ALKALOIDS**

General introduction and classification, isolation and purification methods, general methods employed for determining the structure of alkaloids, constitution of morphine, reserpine and quinine.

2.2 **STEROIDS**

General introduction, stereochemistry, nomenclature and structure elucidation of sterols (cholesterol), sapogenin (diosgenin) and cardiac glycosides.

2.3 **AMINO ACIDS AND PEPTIDES, NUCLEIC ACIDS :**

General introduction, synthesis of peptides and amino acids. End group analysis, structural features of Insulin, vasopressin and oxytocin, structural features of DNA & RNA.

2.4 **ANTIBIOTICS :**

Classification of antibiotics, structural details of penicillins and tetracyclines, polypeptide

antibiotics.

2.5 **FLAVONOIDS :**

Detailed chemical account of rutin and quercetin.

2.6 **TRITERPENOIDS :**

A general chemical treatment and structural elucidation of terpenoids

COUMARINS

General methods of isolation and purification and structural determination of Xanthotoxin and psoralene.

3. Marine products with therapeutic potential.

Books Recommended

1. I.L. Finar, Organic Chemistry, Vol.II, The English Language Books Society and Longman Group Limited.

2. G.A. Cordell, Introduction to Alkaloids, John Wiley and Sons, New York.

3. M.L. Wickery and B. Wickery, Secondary Plant Metabolism McMillan Press Ltd. London.

4. L.F. Fieser and M. Fieser, Steroids, Reinhold Publishing Co. New York.

5. K.B.G. Torsell, Natural Products Chemistry, John Wiley and Sons, New York.

6. J.B. Harborne, Phytochemical Methods, Chapman and Hall, London

7. Burger's Medicinal Chemistry and Drug Discovery, Vol. I. Principle and Practice, 5th, Edition, John Wiley Sons, New York.

Semester No. 2

No. of Teaching : Hrs. 4 Hrs / Week

Paper IV Duration of Exam :3 Hrs.

Max. Marks. :100

PHARMACEUTICAL CHEMISTRY-III MEDICINAL CHEMISTRY

The following topics will be discussed keeping in view the recent advances:

1. Cardiovascular Agents : Anti-hypertensive agents, antiarrhythmic agents, antihyperlipidemic agents, antianginal agents.

2. Psychopharmacological agents : Antipsychotic Agents : Introduction, Biochemical basis of mental disorders, Development of antipsychotic agents : Phenothiazines, Butyrophenones: Atypical antipsychotic agents. Antidepressant Drugs : Introduction, Development of tricyclic antidepressants, Monoamine oxidase inhibitors; Selective serotonin-reuptake inhibitors; Atypical antidepressants, Lithium salts. Antianxiety Agents : Introduction, medicinal Chemistry of benzodiazepines; SAR of benzodiazepine derivatives, medicinal chemistry of non-benzodiazepines; serotonin-reuptake inhibitors, development of meprobamate and analogues; atypical anxiolytic agents;

3. Chemotherapy : Antiviral agents including the development in chemotherapy of AIDS, Drugs for neoplastic diseases.

4. Drug affecting immune responses.

5. Radioprotective drugs

6. Analgesics and anti inflammatory agents, Prostaglandins, Non steroidal drugs, Steroidal drugs, Endorphins

7. Diuretics

8. Chem. of cell membrane; Signal transduction and G. Proteins.

BOOKS RECOMMENDED

1. M.E. Wolf, Brugers Medicinal Chemistry, John Wiley and Sons, New York, Vol. I, II & III

2. R.F. Doerge, Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott.

3. W.O. Foye, Principles of Medicinal Chemistry, Lea and Febiger, Philadelphia.

4. Lednicer and Mitschler, Drug synthesis, Vol. I, II & III.

5. Martindale, The Extra Pharmacopoeia, Pharmaceutical Press, London

6. T, Albert, Selective Toxicity, Chapman and Hall, London.

7. Burger's Med. Chem. & Drug Discovery, Vol. I.

8. Monographs and relevant Review articles appearing in various periodicals and Journals.

Semester No. 2

Practical Duration of Exam: 12 Hrs.

Max. Marks :100

Practicals based on some topics covered in the theory part including synthesis of

medicinal compounds and analysis of organic mixtures will be carried out.

Semester III

Pharm. Chemistry (Practical II) : Practical based on synthesis and spectral analysis of some medicinal compounds. 100 Marks

Semester IV

Thesis of Research Work :300 Marks

Viva Voce :200 Marks

Syllabus For M. Pharm
in
Pharmaceutics
Effective from Session

2002-2003

SEMESTER-I

Paper Modern Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester of the first five branches of M. Pharm course.

Syllabus- As on page No. 14 to 16.

Semester - I

Teaching Hours - 4 Hrs/week

Paper - II

Duration of Exam - 3 Hrs

Maximum Marks - 100

PHARMACEUTICS I PRODUCT DEVELOPMENT AND QUALITY ASSURANCE

1. Preformulation Studies :

Timings and goals of Preformulation, Pre-formulation methodology, solid state properties, partition coefficient, solubility, dissolution, crystal form and stability, compatibility tests, dissolution of drug substances and dosage.

2. Kinetic principles and stability testing :

Order of reaction, influence of pH, temperature, Acid - base catalysis. Effect of Ionic strength on degradation, Complex reactions, amide hydrolysis, Ring alteration, Oxidation - reduction, Chemical &Physical stability of dosage forms, Influence of packaging components on dosage form stability.

3 . Optimization Techniques in Pharmaceutics, Formulation and Processing

Optimization parameters, statistical design, and other application.

4. Documentation

Relevance and importance of documentation, statuary requirements and procedure for documentation, critical examination of documents.

5. Pharmaceutical Process Validation :

Regulatory basis, Validation of sterile products, Solid dosage forms, Process Validation and non-sterile Analytical method Validation.

6. Quality Control : Process of dosage forms :

Process control ; Control of quality Validation, Control of manufacturing Process, Statistical quality control, control charts, sampling plans, Automated & process control, Dosage form control, Testing programme & method, Product identification systems, Adulteration, Misbranding, maintenance of records, Bioavailability, Bioequivalence, manufacturer's reliability, Manufacturer/drug information profile.

Books Recommended :

1. Lachman, Leon and H. A. Lieberman, The theory and Practice of Industrial pharmacy, 3rd edition, Varghese Publishing Co.

2. Gilbert S. Banker and C.T Rhodes, Modern Pharmaceutics, Marcel Decker.

3. Bernard T. L. and Robert A. Narth, Pharmaceutical process validation, volumes 23, Marcel Decker.

4. Norman A., Hodges and Stephen P. Denyer, haul book of Microbiological Quality control, Tayler and Francis, London.

5. Horth Tonneson, Photostability of Drugs and Drug Formulations, Taylor and Francis, London.

Pharmaceutics I Practicals

To illustrate the topics included under theory.

Semester – II

Teaching Hours - 4 Hrs/week

Paper - III Duration of Exam - 3 Hrs

Maximum Marks - 100

Pharmaceutics II - Industrial Pharmacy and Packaging Technology

1. General Consideration, Preparation of Master Manufacturing Procedure

Material Handling, Blending, Granulation, Drying, Slugging Compression, Coating liquid Dosage Forms Contract Manufacturing

2 . Production and Planning Management

Space Allocation, environmental factors, Manufacturing, Materials

Management, Sales forecasting, Cost Control.

3. Drug Regulatory Methods

Definitions ; Federal food, Drug and Cosmetic Act ; Kafaurver Harre's Amendments, New Drug Application, Drug efficacy study, Implementation Review, OTC Drug review, Drug Listing. Drug amendments, Patents, Copy right, Trade Marks, Drug recalls,

product liability, Clinical Trials.

4 . Good Manufacturing Practices

GMP in manufacturing, Processing, Packaging and holding of Drugs ; Control of Components, Containers and closures, Production and process controls : Packaging & labeling controls ; Inspection for compliance with GMP Potable water standards ; Premises : Design, Construction, maintenance, equipment ; maintenance, warehousing, . ISO 9000 certification.

5 . Polymers and their application

Nomenclature, Polymer classification, Physicochemical properties, Chemistry, blends of polymer and properties of blends, Evaluation of polymers, Medical and surgical applications of polymers, polymerization mechanisms, Polymerization methods, Properties of Polymers & their characterization, Mechanism of Drug release from polymers, Applications of Polymers in controlled release of active agents and in other formulations.

6 . Packaging materials science

Packaging design and specifications, packaging validation trials, material of construction, component product validation, Regulatory requirements, Quality control Testing and Standards, GMP requirements & its deficiencies ; In process control during component manufacture Documentation ; Sterilization of packaging components ; Packaging and filling equipment ; Pharmaceutical Packaging including sterile filling area ; customer complaints.

Books Recommended :

1. Lachman Leon & H. A. Liberman, The theory and practice of Industrial Pharmacy,

Varghese Publishing Co.

2. Gilber S. Banker and C. T. Rhodes, Modern Pharmaceutics Marcel Dekker Inc.

3. Kenneth Harburn, Quality Control of Packaging materials in the pharmaceutical Industry.

4. Sidney H. Willing, Good Manufacturing Practice for pharmaceuticals, Mercel Decker Inc.

5. Kinam Park, Shalaby. S. W, and Haesun park, Biodegradable Hydrogel for Drug Delivery, Technomic Basel.

6. Armstrong, N. A. and James K. C. , Pharmaceutical Experimental Design and Interpretation, Taylor and Francis, London.

7. Brody, A. L. and Marsh , K.S. , Encyclopedia of Packaging Technology, John wiley and sons, New York.

Pharmaceutics I Practical

To illustrate the topics included under theory.

Semester – II

Teaching Hours - 4 Hrs/week

Paper - IV Duration of Exam - 3 Hrs

Maximum Marks - 100

Pharmaceutics III - Advances in Drug Delivery Systems :

1. Fundamentals of Controlled release drug delivery systems :

Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.

2 . Design & Fabrication of Controlled Drug Delivery Systems :

Novel chemical approaches for sustained drug delivery, Design & fabrication of oral controlled release drug delivery systems. Parenteral products, Implantable systems. Transdermal systems, ocular , Intra - Vaginal, intra - uterine systems.

3 . Biochemical and Molecular Biology approaches Controlled Drug Delivery :

Microparticulate drug Carriers ; Liposomes, Microspheres and cells, selective endocytosis of macromolecular drug carriers, Antibodies for drug delivery, Resealed

erythrocytes, Niosomes.

4 . Advances in the monitoring of pharmacotherapeutics and in drug delivery system design.

Books Recommended :

1. Robinson & Lee, Controlled Drug Delivery Fundamentals & Applications, Volume 29, 2nd edition, Marcel Dekker Inc.

2. James Swarbrick, Novel Drug Delivery Systems.

3. Gilbert S. Banker and C. T. Rhodes, Modern Pharmaceutics 2nd Edition.

4. Robinson J. R. and Vincet H. L Lee, Controlled Drug Delivery, Fundamentals And Applications, Volume 29, 2nd edition, Mercel Dekker Inc.

5. Avis, K. E, Leon Lachman, And H. Lieberman, Pharmaceutical Dosage Forms : Parenteral Medications Volume - 2.

6. Lierberman H. A. and Leon Lachman , Pharmaceutical Dosage Forms : tablets Volume 3, Marcel Dekker.

7. Scher, H. B., Controlled release Delivery Systems of Pesticides, Marcel Dekker.

8. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.

Pharmaceutical I Practical :

Maximum Marks : 100

To illustrate the topics included under theory.

Semester – III

Pharmaceutics Practical-II Marks : 100
· --Synopsis of Research Project
· --Seminar & Viva Voce on Research methodology & Research project

Semester - IV

Thesis - 300 Marks

Viva Voce - 200 Marks

Syllabus For M. Pharm
in

Pharmacognosy & Phytochemistry

Effective from Session

SEMESTER-I

Paper Modern Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester of the first five branches of M. Pharm course.

Syllabus- As on page No. 14 to 16

Semester-I

Teaching Hours - 4 Hrs/week

Paper - II Duration of Exam - 3 Hrs

Maximum Marks - 100

PHARMACOGNOSY & PHYTOCHEMISTRY-I

(**Advances in Pharmacognosy**)

1. Genetics in Pharmacognosy :

Mendal's laws of hereditary and their application to Pharmacognosy, Chemical races, Selections, Hybridization, Polyploidy, mutation, plant growth hormones, their application and effect on plant growth and its constituents.

2. Chemotaxonomic significance in medicinal plants :

History of Chemotaxonomic developments. Chemotaxonomy of higher and lower plants and distribution of certain chemotaxonomical group of constituents in plant kingdom like alkaloids, glycosides and terpenoids.

3. Comparative Phytochemistry :

Relationship between Phytochemistry and Taxonomy. Comparative Phytochemistry of alkaloids, flavonoids and C-glycosides.

4. Plant Tissue Culture techniques and its application in relation to Phytopharmaceuticals :

Introduction, techniques of initiation and maintenance of various types of cultures. Immobilized cell techniques, Biotransformation studies including recent developments in production of biological active constituents in static, suspension and hairy root cultures, Bioreactors for production of biologically active constituents and other applications of plant tissue culture techniques.

5. Recent advances in the field of Pharmacognosy with special reference to anticancer, antidiabetic, anti-inflammatory, hepatoprotective, adaptogenic and immunomodulating drugs of plant origin. Skin irritants and sensitizing agents from plant and marine products of medicinal importance. Plants sweetners.

BOOKS RECOMMENDED

1. Evans WC (2002) Trease & Evans' Pharmacognosy, WB. Saunders & Co., London.

2. Swain T. (1963) Chemical Plant Taxonomy, Academic Press London.

3. Stace C.A. (1985) Plant Taxonomy and Biosystematics, Edward Arnold, London.

4. Cultivation and Utilization of Medicinal Plants by C.K. Atal, R.R. L. Jammu.

5. Street H.E. (1997) Plant Cell and Tissue Culture, Blackwell Scientific, London.

6. Narayanaswami S. (1997). Plant Cell and Tissue Culture, Madras Science Foundation, Madras.

7. Bajaj Y.P.S. "Biotechnology in Agriculture and Forestry-Volumes 4, 7, 8, 9, 15 (1988-91). Springer -Verlag, Berlin.

8. Takashashi N. (1986). Chemistry of Plant Hormones, CRC Press Inc., Florida

9. Gennaro AR (2000). Remington: The Science & Practice of Pharmacy, Lippincott Williams & Wilkins, Philadelphia.

10. Fitoterapia- (1980 onwards).

11. Planta Medica (1980 onwards).

12. Plant Cell, Tissue and Organ Culture (1980 onwards).

13. Journal of Ethnopharmacology (1980 onwards).

14. Journal of Natural Products (1970 onwards).

15. Phytochemistry (1970 onwards).

Semester-II Teaching Hours - 4 Hrs/week

Paper - III Duration of Exam - 3 Hrs

Maximum Marks - 100

PHARMACOGNOSY & PHYTOCHEMISTRY-II

(**Phytochemistry & Biogenesis**)

1. General methods of phytochemical & biological screening, isolation and purification of plant constituents.

2. Natural sources, extraction, purification, isolation and characterization of the following Phytopharmaceuticals.

Alkaloids : Morphine, Quinine

Glycosides : Sennosides, Glycyrrhizine, Asiaticosides, Diosgenin, Solarodine, Rutin

3. Industrially important volatile oils : Natural occurrence, their chemistry, ontogenic variation and trade.

4. Methods of investigation of biogenetic pathways.

5. Biogenetic pathways for the production of phytopharmaceuticals, such as Alkylamine (Ephedra), Pyridine, Piperidine (Lobelia), Tropane (Belladonna), Quinoline (Cinchona), Isoquinoline (Opium), Diterpene (Aconite), Indole (Ergot), Cardiac glycosides, Coumarins and Flavones.

6. Study of some herbal formulation as drug and cosmetics.

BOOK RECOMMENDED

1. Evans WC (2002) Trease & Evans' Pharmacognosy, W.B. Saunders & Co., London.

2. Natural Products for Plants by Kaufmann, CRC Press New York.

3. Cultivation and Utilization of Medicinal & Aromatic Plants by C.K. Atal and B.M. Kapur, R.R.L. Jammu.

4. Pharmacognosy by Tyler and Brady, Lea & Febiger, Philadelphia.

5. Herbal Medicines by Jonne Bernes, Pharmaceutical Press, London.

6. Medicinal Plants in Skincare by Sushil Kumar, CIMAP, Lucknow.

7. Nakanishi K (1977). Chemistry of Natural Products, Kodansha Book Publishing Company, Osaka (Japan).

Semester-II Teaching Hours - 4 Hrs/week

Paper - IV Duration of Exam - 3 Hrs

Maximum Marks - 100

PHARMACOGNOSY AND PHYTOCHEMISTRY-III

(Cultivation & Standardization of medicinal plants)

1. Preparation of herbarium specifications, use of flora and keys of plant identification, Microtomy and advanced histological techniques as applied to pharmacognostical specimen, pharmacognostical drawings and macro and micro photography. Quantitative microscopy as applied to drug evaluation and pollen grain analysis.

2. Agrotechnology of medicinal plants ; Ecotypic, Phenotypic and Genotypic Variability affecting phytopharmaceuticals. Prospects and economics and medicinal and aromatic

plants in India. Cultivation methods developed in India for the following plants of commercial significance. Glycyrrhiza, Ipecac, Mentha, Poppy, Psyllium and Senna. Tropane alkaloid and steroid containing plants.

3. Application of chromatographic techniques such as column, paper, TLC, HPTLC, GLC, HPLC and DCCC in the isolation and purification of phytopharmaceuticals.

4. Applications of UV, IR, NMR, 1HNMR, 13CNMR and Mass spectroscopy for structural elucidation of phytopharmaceuticals. Standardization and quality procedures for the assay of plant products.

BOOKS RECOMMENDED

1. Chromatography by Heptman.

2. Techniques in Terpenoid Identification by Dr. Mohd. Ali, Birla Publications, Delhi.

3. Cultivation and Utilization of Medicinal & Aromatic Plants by C.K. Atal and B.M. Kapur, R.R.L. Jammu

4. The Wealth of India (Raw Materials) All Volumes, NISCOM, Delhi.

5. Stahl. E. (1987). Thin Layer Chromatography, Springer-Verlag, Berlin-Hiedelberg-New York.

6. Anonymous (1993) Standardisation of Single Unani Drugs, CCRUM, New Delhi.

Semester II

PHARMACOGNOSY & PHYTOCHEMISTRY PRACTICAL - I

List of Experiments

1. Isolation of Rutin from Fagopyrum species, Hesperidin from Orange peel, Aloin from Aloes, Rhein from rhizome of Rheum species, Piperine from Piper nigrum, Quinine from Cinchona bark, Berberine from Berberis aristata, Caffeine from Tea leaves, Menthol from Mentha species, Diosgenin from Dioscorea and Trigonella species. Determination of Anthracene derivatives in Senna by spectrophotometric method (Fair Buarian 1975), Reserpine in Rauwolfia by photometric method, Quinine in Cinchona bark, Thevetia seeds / bark calculated in terms of digitoxogenin by photometric method, Carvone content of Umbelliferous fruits, Citral content in Lemon grass oil, Bitter principles of Chirata, Solanaceous drugs, Tropane alkaloids using Vitali Morin reaction, quanititative estimation of Saponin as per W.H.O. protocol in suitable plant material, Resin content in sample of Podophyllum by B.P.C. method, Optical rotation of oil of Lemon, Acid value of Colophony resin by B.P. method. Swelling factor of husk and seeds of Isaphgol, Moisture content of Acacia by toluene distillation methods, Water soluble extractive values of sample of Cascara B.P. method, extractive value of sample of Rhubarb or Ginger, Iodine values of Arachis oil, TLC of volatile oil samples, Antimicrobial activity of some volatile oils, Phytohaematoglutinin activity of extract of some seeds. Examination of Rhubarb for the presence of Rhapontic Rhubarb by the use of paper chromatography and ultraviolet light. Separation of Solanaceous alkaloids from Belladonna leaf by TLC using hyoscine and hyoscyamine as reference compound,

anthracene glycosides of Senna leaf by paper chromatography. Isolation of Solanaceous alkaloids over alumina column. To develop callus culture of Senna on Wood and Brauin's medium, the root culture of Trigonella foenum-graecum on Street & McGroger medium.

Semester III

PHARMACOGNOSY & PHYTOCHEMISTRY PRACTICAL II

List of Experiment

1. Determination of Ascorbic acid (Vitamin C) by UV. Spectroscopic method in crude drugs.

2. Determination of Hyoscymine/Hyoscine in Datura species by UV. Spectroscopic method.

3. Quantitative estimation of Reserpine in Rauwolfia serpentina by HPLC method.

4. Quantitative estimation of Quinine in Cinchona bark by HPLC method.

5. Quantitative estimation of Ephedrine in Ephedra extracts by HPTLC.

6. Quantitative estimation of glycyrrhizine in Glycyrrhiza glabra by HPTLC.

7. Exercises on Identification of simple Naturally occurring molecules by UV. & IR spectroscopy.

8. Exercises on interpretation of at least 5-different known compounds of Natural origin by using spectroscopic data (NMR & MASS)

9. Preparation of permanent microscopic slides and section cutting by microtone

10. Determination of Microbial load in Crude drugs.

11. Separation and identification of aflotoxins in Crude drugs.

12. Preparation of detailed monograph of at least one medicinal plant covering taxonomy, phytochemical and pharmacological investigation and its use in traditional system of medicine.

Semester-IV

Thesis :300 Marks

Viva Voce :200 Marks

Effective from Session

2002-2003

Paper I Modern Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester of the first five branches of M. Pharm course.

Semester –I

Number of Teaching Hrs. (4 Hrs/week)

Paper-II Duration of Exam : 3 Hrs.

Max. Marks 100

Pharmacology – I

Basic Principles of Drug Therapy,and Clinical Pharmacology

I. Definition, Scope, Organization and growth of Clinical Pharmacology, Cellular Transduction Mechanisms, Clinical Pharmacokinetics, Monitoring of Drug Therapy, Adverse Drug Reactions, Patient Compliance, Pharmacogenetics, Paediatric and Geriatric Pharmacology, Drug Interactions, Drug Therapy during pregnancy and lactation.

II. Drugs acting on the autonomic nervous system :

i) Neurotransmission : The Autonomic and Somatic Motor Nervous System.

ii) Muscarinic Receptor Agonists and Antagonists.

iii) Anticholinestrase Agents

iv) Agents acting at the neuromuscular junction and autonomic ganglia.

v) Catecholamines, Sympathomimetic Drugs and adrenergic receptor antagonists, Ocular Pharmacology.

vi) 5-Hydroxy tryptamine (Serotonin) receptor agonists and antagonists.

III. Drugs acting on the Central Nervous System

i) Neurotransmission and the Central Nervous System

ii) History and Principles of Anesthesiology

iii) General Anesthetics

iv) Local Anesthetics

v) Hypnotics , Sedatives and Ethanol

vi) Drugs and the treatment of Psychiatric Disorder : Psychosis, Anxiety : Depression and Mania

vii) Drugs Effective in the therapy of Epilepsy

viii) Drugs effective in the therapy of Migraine

ix) Treatment of Central Nervous system degenerative disorders

x) Opioid Analgesics and Antagonists

xi) Drug Addiction and Drug Abuse

IV. Autocoids : Drug Therapy of Inflammation

i) Introduction

ii) Histamine, Bradykinin and their Antagonists

iii) Lipid- Derived Autocoids : Eicosanoids and platelet Activating factor

iv) Analgesic-Antipyretic and Anti-Inflammatory agents and Drugs employed in the treatment of Govt.

v) Drugs used in the treatment of Asthma.

V. Drugs effecting renal, blood and cardiovascular function :

i) Diuretics

ii) Drugs used in the treatment of Myocardial Ischemia

iii) Antihypertensive agents and the drug therapy of hypertension.

iv) Pharmacological treatment of Heart Failure

v) Antiarrhythmic Drugs

vi) Drugs used in the treatment of Hyperlipoproteinemias

vii) Heamatopoietic Agents : Growth factors, Minerals and Vitamins

viii) Anti coagulant, thrombolytic and antiplatelet drugs.

BOOKS RECOMMENDED

1. Modern Pharmcology by C.R. Craig and R.E. Stitzel

2. Goodman and Gilman's : The Pharmcological Basis of Therapeutics, edited by Alfred

Goodman Gilman, Theodore W. Rall, Alan S Nies, and Palmar Taylor

3. Clinical Pharmcology by D.R. Laurence and P.N. Benett

4. Essentials of Pharmcotherapeutics by F.S.K. Barar

5. Pharmacology by H.P. Rang and M.M. Dale

6. Lewis's Pharmacology revised by James Crossland

7. Oxford Textbook of Clinical Pharmacology and Drug Therapy by D.G. Grahame-Smith and J.K. Aronson.

PRACTICAL

Pharmacological techniques employed in the study of various drugs.

Semester-II Number of teaching Hrs. (4 Hrs./Week)

Paper-III Duration of Exam : 3 Hrs.

Max Marks : 100

Pharmacology II Recent advances and emerging Trends in Pharmacological Sciences.

(Theory)

I. Digestive System

a) Pharmacotherapy of peptic ulcer, diarrhoea, constipation.

b) Agents affecting gastrointestinal water, Flux and motility : Emesis and antiemetics; Bile acids and Pancreatic enzymes

II. Therapy of Infectious diseases

a) General Principles, Antibacterial Drugs Sulphonamides, Quinolones, Penicillins, Cephalosporins, Tetracyclines, Chloramphenicol.

b) Drugs used in the chemotherapy of Protozoal infections: Malaria

c) Drugs used in the chemotherapy of Protozoal infections : Trypanosomiasis, Leishmaniasis, Amebiasis, Giardiasis, Trichomoniasis, and other Protozoal infections.

d) Drugs used in the chemotherapy of Helminthiasis

e) Drugs used in the chemotherapy of Leprosy, Tuberculosis, Fungal infections, Viral infections

f) Drugs used in the Chemotherapy of Neoplastic diseases

g) Immunomodulators : Immunosuppressive agents and Immunostimulants

h) Newer Chemotherapeutic agents

III. Hormones and Hormones Antagonists

a) Adenohypophyseal hormones and their Hypothalamic releasing factors.

b) Hormones of Posterior pituitary

c) Thyroid and Antithyroid drugs

d) Estrogens and Progestins, Antifertility agents

e) Androgens

f) Adrenocorticotropic hormones; Adrenocortical steroids and their synthetic analogs; Inhibitors of the synthesis and actions of adrenocortical hormones.

g) Insulin, oral hypoglycemic agents and the Pharmacology of pancreatic hormones.

h) Agents affecting Calcification and bone turnover:

Calcium phosphate, parathyroid hormones, vitamin D, Calcitonin and other compounds.

i) Vasopressin and other agents affecting the renal conservation of water.

IV. Emerging Trends & Recent advances in:

a) Receptor and G-Protein

b) Cyclic neucleotides

c) TNF, Apoptosis

d) Ion channel modulators

e) Neurosteroids and Cannabinoids

f) Nitric oxide

g) ANF, Anti oxidants : Melatonin

h) Chiral Pharmacology

i) Gene therapy

j) Neuropeptide, Substance P, Angiotensin II modulators.

RECOMMENDED REFERENCE JOURNALS

1. Annual Review Pharmacology and Toxicology

2. Drugs

3. Pharmacological Reviews

4. Trends in Pharmacological Sciences

5. Indian Journal of Physiology & Pharmacology

6. Indian Journal of Experimental Biology

7. Indian Journal of Pharmacology

Semester-II

Number of teaching Hrs. (4 Hrs./Week)

Paper-IV Duration of Exam. 3 Hrs.

Max. Marks 100

Pharmacology III Pharmacological methods and Toxicology (Theory)

1. Principles of Pharmacological and Clinical Evaluation of drugs.

2. Pharmacological Techniques to evaluate drugs belonging to following categories.

a) Antipsychotics, antianxiety agents; nootropics; antidepressants, antiparkinsonian agents, antiepileptics, analgesics, anti-inflammatory agents, local anaesthetics.

b) Antihypertensives, antiarrhythmics, antiatherosclerotics, drugs for myocardial infarction.

c) Antiulcer drugs, antidiabetics, antitussives

d) Evaluation of antioxidants

e) Transgenic animals, genetically prone animal models

f) Anti cancer drugs

g) In-vitro techniques

h) Antifertility agents

3. Drug Toxicity, Safety Evaluation of new drugs

4. Regulations for Laboratory animal care and ethical requirements

BOOKS RECOMMENDED

1. Modern Pharmacology by C.R. Craig and R.E. Stitzel

2. Goodman and Gilman's : The Pharmacogical Basis of Therapeutics edited by Alfred Goodman Gilman, Theodore W. Rall, Alan S. Nies and Palmar Taylor

3. Clinical Pharmacology by D.R. Laurence and P.N. Benett

4. Essenticals of Pharmactherapeutics by F.S.K. Barar

5. Pharmacology by H.P. Rang and M.M. Dale

6. Lewis's Pharmacology revised by James Crosslang

7. Oxfor Textbook of Clinical Pharmacology and Drug Therapy by D.G. Grahame Smith and J.K. Aronson

Semester-II

PHARMACOLOGY PRACTICAL-I

Duration of Exam. 12 Hrs.

Max. Marks 100

(I)

a) Study of agonist and antagonist

b) pD2 Value

c) pA2 Value

d) 5HT bioassay (Comparative, graphical, 4 point)

e) Oxytocin bioassay (Graphical)

f) Antagonist bioassay

g) Ach bioassay (rat fundus)

h) Histamine assay guinea pig ileum (Graphical & 4 point assay)

i) Blind screening of drugs.

(II)

Estimation of drugs in body fluids using modern analytical techniques.

BOOKS RECOMMENDED

1. Fundamentals of Experimental Pharmacology by M.N. Ghosh

2. Screening Methods in Pharmacology, Vol I & II, edited by Robert A. Turner and Peter Hebborn

3. Textbook of invirtro Practical Pharmacology by Ian Kitchen

4. Evaluation of Drug Activities : Pharmacometrics, Vol I & II, edited by D.R. Laurence and A.L. Bacharah

5. Selected Topics in Experimental Pharmacology by U.K. Sheth, N.K. Dadkar and Usha G. Kamat

6. Pharmacological Experiments of Isolated preparations by Edinburgh University Pharmacology Staff, 1968

7. Analytical procedures for Therapeutics Drug Monitoring and Emergency Toxicology by Randall C. Baselt

8. Frontiers in Therapeutics Monitoring, edited by Gianni Tagnoni, Roberto Latini and William J. Jusko

9. Drug-Bioscreening Drug Evaluation Techniques in Pharmacology in Emmanuel B. Thompson

Semester III (Marks 100)

PHARMACOLOGY PRACTICAL-II

I. Screening methods in Pharmacology:

Screening of antipsychotics, antianxiety, nootropics, antidepressants, antiparkinson, antipileptics, analgesics, anti-inflammatory, antihypertensive, anti MI, anti ulcer, antidiabetic and antioxidants.

II. Literature survey, preparation of synopsis of the project work.

III. Seminar on the project work.

Books Recommended

1. Fundamentals of Experimental Pharmacology by M.N. Ghosh, Scientific Book Agency, Calcutta (1984)

2. Pharmacological experiments in Intact preparations Edinburgh University

Pharmacology Staff, Livingstone (1968).

3. Pharmacological Experiments on isolated preparations, Edinburgh University Pharmacology Staff,

Livingstone (1968)

4. Handbook of Experimental Pharmacology by S.K. Kulkarni, Vallabh Parakashan Delhi, 3rd Edition (1999)

5. Screening Methods in Pharmacology by P. Turner, Vol. I & II, Academic Press, New York and London (1965)

6. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springer-Verlag, Berlin Heideleberg (1997)

Semester IV

Thesis 300 Marks

Viva Voce 200 Marks

Syllabus for M. Pharm.
In
Quality Assurance

Effective from session

2002-2003

SEMESTER-I

Paper I Modern Pharmaceutical Analytical Techniques (Theory & Practical) is common subject in the first semester of the first five branches of M. Pharm course.

Semester - I

Paper - II

QUALITY ASSURANCE – I

Teaching Hours : 4 Hrs/Week

(Product Development and Packaging)

Duration of Exam :3 Hrs

Maximum Marks : 100

Section – A : 50 Marks

Section – B : 50 Marks

Section A : Product Development

1. Preformulation Studies : pKa and solubility kinetics, pH profile, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristic, dissolution, compatibility studies, protocol for Preformulation studies.

2. Drug stability: Solution stability, solid state stability, parameters for physical stability testing. Accelerated stability & shelf life assignment of drugs and pharmaceuticals.

3. Tablets Technology: Formulation, manufacturing and evaluation with special emphasis to unit process involved including mixing, drying, size reduction, granulation technology, compression & compression coating.

4. Coating of Solid Dosage Form : Aqueous and non-aqueous film coating, polymers, process controls, coating equipments, coating pans, Accela coata, Hi-coater, Driacoater, Fluid bed coating, equipment e.g. Glatt & Kugel coater application and metering equipment, particle coating methods, pelletization.

5. Encapsulation Technology: Gelatin, physical and chemical properties, additives, substitutes, manufacture of hard gelatin capsules, capsule printing machinery and operation involved in dry filling powders, semisolid, and liquids in capsules.

6. Liquid Dosage Forms: Formulation, stabilization and evaluation of liquid dosage forms including suspensions and emulsions, processing and equipment used in manufacture.

7. Parenteral Technology: Formulation, stabilization and manufacture of small and large volume Parenterals, stabilization evaluation and quality control, Environmental controls and design consideration for parenteral production facility, freeze drying.

8. Dissolution Technology: Dissolution testing devices viz. forced convection non-sink devices, continuos flow through methods, effect of environmental factors during dissolution testing. Dissolution rate test apparatus for suspensions, topical and transdermal products, suppositories and controlled release products. In-Vitro-in-Vivo correlations.

9. Introduction to New Drug Delivery systems and their evaluation : Oral, Mucosal, Ocular, Transdermal , site specific and injectable controlled release systems

Section B : Packaging

1. Glass and plastic containers for Pharmaceuticals: types, their manufacture, chemical performance, testing, quality control and biological toxicity. Flexible packaging, Type of films, Co-extracted films.

2. Paper and paper board : Types of paper, folding cartons, Quality control testing of paper and paper board.; Corrugated and solid fiber boards and boxes

3. Metal Container: Aluminium and tin-plated drums, collapsible tubes and Aerosol containers. (lacquering, coating and lining)

4. Caps and Closures: Types of caps closure liners, child - resistant caps. Elastometric closure for parenterals, classification of elastomers, physical, chemical and biological properties and their quality control.

5. Labels and Labeling: Types of labels, adhesives, inkjet and bar-coding.

6. Packaging Machinery including strip packing, blister packaging, form, fill and seal machines, liquid and solid filling machines, capping machines.

7. Product-package compatibility, stability of product, packaging selection and critical development.

8. Tamper resistant packaging systems.

BOOKS RECOMMENDED

1. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.

2. Handbook of Pharmaceutical granulation technology, Vol. 81, by Patrich, Marcel Dekker.

3. Microparticulate Systems for the delivery of proteins & vaccines, Vol. 77, by Smadar Cohen & H. Bernstan, Marcel Dekker.

4. Controlled Drug Delivery : Concepts & Advances by Prof. S. P. Vyas & Prof. Roop K Khar, Vallabh Prakashan, Delhi.

5. Targeted & Controlled Drug Delivery ; Novel Carrier Systems, By Prof. S. P. Vyas && Prof. Roop K Khar, CBS Publishers, Delhi.

6. Pharmaceutical dosage Forms - Disperse Systems, Vol. 1, 2 & 3, Herbert A. Lieberman, Martin M. Reiger, Gilbert S. Banker, Marcel & Dekker Inc, New York.

7. Pharmaceutical Dosage forms - Parenteral Medications, Vol 1 -3, Kenneth E. Avis, Herbert A. Leiberman, Leon Lachman, Marcel Dekker Inc., New York.

8. Introduction to Pharmaceutical Dosage Forms, Hourared C. Ansel, 4th edition, Varghese Publishing, Bombay.

9. Pharmaceutical Dosage forms - Tablets, Vol. 1-3, Herbert A. Lieberman, Leo Lachman, Joseph B. Schurartz, Marcel Dekker, Inc., New York.

10. Quality control of Packaging Materials in the Pharmaceutical Industry, Kenneth Herburn, Marcel Dekker, Inc., New York.

11. Pharmaceutical Peletilization Technology, Vol. 37, by Ghebre -Sellassie, Marcel Dekker. New York.

12. Controlled Drug Delivery, Fundamentals of Application, 2nd edition, Vol. 29, #

Joseph R. Robinson, Vincent H. L. Lee, Marcel Dekker Inc., New York.

13. Controlled Drug Delivery Vol. I by N. K. Jain, CBS Publisher, New Delhi. 25 Controlled Drug Delivery Vol. II by N. K. Jain, CBS Publisher, New Delhi.

14. Ophthalmic Drug Delivery Systems, Vol. 58 by A. K. Mitra, Marcel Dekker., New York.

15. Bioadhesive drug delivery systems, Vol. 98, by Mathiowitz., Marcel Dekker.

16. Pharmacokinetics, Vol. 15, 2nd edition, by Gibaldi & Perrier, Marcel Dekker.

17. Controlled drug bioavailability, Vol. 3, by Smolen Ball, Witley Interscience.

18. Textbook of Biopharmaceutics and Pharmacokinetics by Javed Ali, Roop K Khar and Alka Ahuja, Birla Publications, New Delhi

19. Clinical Pharmacokinetics, by Rowland, Malcolm and Tozer, Lea Febigar, Philadeliphia, 1980.

20. Textbook of Hospital and clinical Pharmacy by Pratibha Nand and Roop K Khar Birla Publications, New Delhi

21. Pharmaceutical Dispensing by Pratibha Nand and Roop K Khar CBS Publishers, New Delhi

22. P.P.Sharma, Cosmetics-Formulation Manufacturing and Quality Control, Vandana Publications, Delhi,1998.

23. E.A.Rawlins, Bentley's Textbookn of Pharmaceutics, University Printing House, Oxford, 1998

24. Inhalation Delivery of Therapeutic Peptides & Proteins, by Adjel, (Marcel Dekker).

25. Liposomes: Rational Design, by Janoff, (Marcel Dekker).

26. Peptide and Protein Drug Delivery, by Lee, (Marcel Dekker).

Semester - II

Paper - III

QUALITY ASSURANCE – II

Teaching Hours : 4 Hrs/Week

(Biological Evaluation and Validation) Duration of Exam : 3 Hrs

Maximum Marks : 100

Section – A : 50 Marks

Section – B : 50 Marks

Section A : Biological Evaluation

1. Microbiological Limit Tests.

2. Sterility Tests : Methodology & Interpretation

3. Refer section B (Validation) - repeated

4. Tests for effectiveness of antimicrobial preservatives

5. Preclinical Drug Evaluation, acute, subacute and chronic toxicity, Evaluation of a compound for its biological activity, and ED 50 determination. Special toxicity tests like teratogenicity and mutagenecity, Clinical Trials. Introduction to G.C.Ps

6. Biological standardization: General principles, scope and limitations of bioassays, Bioassays of some official drugs.

7. Radio immunoassay: General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc.

8. Pyrogen - chemistry and properties of bacterial pyrogens and endotoxins, Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogens test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL & other pyrogens tests.

9. Animal Studies.

10. Drug Approval., Schedule-Y; Introduction to U.S; F.D.A's, N.D.A/A.N.D.A

11. Introduction to Bioequivalence studies U.S.P

Section B :

Validation:

1. Validation of Analytical Methods, Calibration of Instruments and equipment.

2. Regulatory considerations in validation

3. Validation of process (Sterile and non sterile products). Validation of sterilization methods equipment, Autoclaves, dry heat sterilisers, aseptic membrane filtration

4. Introduction to validation of manufacturing facilities I.Q./O.Q./and certification, preparation of validation protocols

5. Validation of purified water system, distilled water and water for injection

6. Validation of air handling ‘system, sterile’ and non sterile areas

7. Introduction to validation of computer assisted process.

BOOKS RECOMMENDED

1. Introduction to the environmental Monitoring of Pharmaceutical Areas by Michel Jahnke, Davis Harwood International Publishing.

2. Microbiological Risk Assessment in Pharm. Clean rooms by Bengt Ljunggvist and Berit Davis Harwood International Publishing.

3. Microbiology in Pharmaceutical Manufacturing by Richard Prince, Davis Harwood International Publishing.

4. Understanding Active Pharmaceutical ingredients by Siegfried Schmitt, Davis Harwood International Publishing.

5. Quality control of Packaging Materials in the Pharmaceutical Industry, Kenneth Herburn, Marcel Dekker, Inc., New York

6. Pharmaceutical Process Validation, Volume 23, 2nd edition, Bernard T. Lofters, Robert A. Nash, Marcel Dekker, Inc. New York.

7. Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing, 2nd Edition by Akers, (Marcel Dekker).

8. Handbook of Polymer testing, by Brown, (Marcel Dekker).

9. Pharmaceutical Excipients, by Bugay, (Marcel Dekker).

10. Peptide and Protein Drug Analysis, by Reid,(Marcel Dekker).

11. Lipoproteins as Carriers of Pharmaceutical Agents, by Shaw, (Marcel Dekker).

12. Stability Indicating HPLC Methods for Drug Analysis, by XU, (Pharmaceutical Press Titles).

Semester - II

Paper - IV

QUALITY ASSURANCE – III

Teaching Hours : 4 Hrs/Week

(Quality Management) Duration of Exam : 3 Hrs

Maximum Marks : 100

Section – A : 50 Marks

Section – B : 50 Marks

1. Concept of Total quality management philosophy and GMPs and GLPs, ISO 9000, Introduction to ICH process

2. Organization and personnel, responsibilities, training, hygiene, personnel, records

3. Premises: Location, Design, plant layout. Construction maintenance and sanitation environmental control, utilities and services like gas, water maintenance of sterile areas control of contamination

4. Equipment, selection, purchase specifications, maintenance, clean in place and sterilize in place methods (TP and STP)

5. Raw materials, purchase, specifications, stores, selection of venders Control of Raw materials.

6. Manufacture of and control on dosage forms. Manufacturing documents. Master formula. Batch formula records, standard operating procedure. Quality audits of manufacturing processes and facilities.

7. In process quality controls on various dosage forms sterile and non-sterile standard operating procedure for various operations like cleaning, filling, drying, compression, coating, disinfection, fumigation, sterilization, membrane filtration etc.

8. Packaging and labeling controls. Line clearance, reconciliation of labels, cartons and other packaging materials (refer section B-Validation).

9. Quality control laboratory, responsibilities, good laboratory practices, routine controls, instruments, reagents, sampling plans, standard test procedure, protocols, non-clinical testing, controls on animal house.

10. Data generation and storage. Quality control documentation. Retention samples, records, audits of quality control facilities

11. Finished products release, quality review, quality audits, batch release documents

12. Warehousing, good Warehousing practices, materials management.

13. Distribution and distribution records. Handling of returned goods. Recovered materials and processing.

14. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents

15. Waste disposal, scrap disposal procedures and records

16. Regulatory aspects of pharmaceutical and bulk drug manufacturing.

17. Loan licenses (contract manufacture)

18. Recent amendments to drugs and cosmetics Acts and other relevant rules. Consumer protection. Environmental protection. Factory Act. Certificate and licensing procedures.

19. WHO Certification, Globalization of drug industry, Introduction to export and import policy of drugs

20. Intellectual property rights, patents, trade Marks, copy rights, Indian patent act.

21. Quality Audits: Raw Materials, Finished Products & Analytical Procedures.

BOOKS RECOMMDNED

1. The internal quality audit by Monica Girmaldi and Janet Gough Davis Harwood International Publishing.

2. Validation Master plan by Terveeks or Deeks, Davis Harwood International Publishing.

3. Validation of Asceptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).

4. Statistical Design and Analysis in Pharmaceutical Science, by Chow, (Marcel Dekker).

5. Automation & Validation of Information in Pharmaceutical Processing, by deSPAUTZ, (Marcel Dekker).

6. Guidelines for Laboratory Quality Auditing, by Singer,(Marcel Dekker).

7. Pharmaceutical Experimental Design, by Lewis, (Marcel Dekker).

8. New Drug approval process, 2nd edition, Vol. 56, by Guarino, Marcel Dekker., New York.

9. Hosting a compliance Audit by Janet Gough Davis Harwood International Publishing.

LIST OF EXPERIMENTS FOR M. PHARM. PRACTICALS - Quality Assurance (Suggestive)

1. Preparation and evaluation of Riboflavin/Ibuprofen tablets I .P. to characterize and evaluate the effect of different concentrations of binders and disintegrant.

2. Optimization of tablet formulation of poorly water-soluble drugs.

3. Design and fabrication of theophylline sustained release formulation and comparison of its release profile with the conventional dosage form.

4. Formulation and evaluation of micronized disperse system for parenteral delivery of drugs including test for pyrogens and sterility testing etc.

5. Preparation of solid dispersions of poorly water soluble drugs using different carriers and to study the release profile and compare with conventional dosage forms.

6. Preparation and evaluation of a hydrodynamically balanced drug delivery system of a drug having absorption problem

7. Disintegration and dissolution of per oral tablets

8. Influence of vehicle on drug availability from topical dosage forms in-vitro

9. Determination of Pharmacokinetic parameters and determination and evaluation of bioavailability of a drug administered I.V., I.M. and P.O.

10. Design and preparation of a suspension and its evaluation.

11. Development of moisture resistant coating formulation for Amoxycillin

tablets/ Ranitidine tablets

12. Quality control of paper, Plastic and glass container

13. Quality control of closure

14. Quality control of labels and label adhesives.

15. Microbial limit test in oral products

16. Sterility testing of parenteral products

17. Validation of sterilization equipments e.g. Hot air oven, Autoclave.

18. Validation of Analytical procedure

19. Preformulation studies of a model Drug.

20. Accelerated stability testing and shelf life determination.

21. Biological evaluation of equipments and materials used in sterile or

non-sterile working area.

22. Biological evaluation of sterile and non sterile working area.

Semester III

Synopsis of Research Project

Seminar & Viva Voce on Research methodology & Research Project (Marks 100)

Semester IV

Thesis 300 Marks

Viva Voce 200 Marks