

ORDINANCE, PROGRAMME OF STUDY AND SYLLABUS FOR TWO YEAR
FULL TIME POST GRADUATE DEGREE COURSE IN PHARMACY
[M.PHARM]



University Institute of Pharmacy
Chhatrapati Shahu Ji Maharaj University, Kanpur

UNIVERSITY INSTITUTE OF PHARMACY
C.S.J.M. UNIVERSITY, KANPUR

FACULTY OF PHARMACEUTICAL SCIENCES

MASTER OF PHARMACY (M. Pharm.) in

- 1. Pharmaceutics**
- 2. Pharmaceutical Chemistry**
- 3. Pharmacognosy**
- 4. Pharmacology**

ORDINANCE, COURSE STRUCTURE & SYLLABI

(EFFECTIVE FROM ACADEMIC YEAR 2010-11)

I. NOMENCLATURE: University Institute of Pharmacy will conduct P.G. degree course in Pharmacy (M.Pharm) shall be a four semester full time Course with each semester having duration of six months with a minimum of 90 working days. The M.Pharm Course shall have the following specializations :

1. Pharmaceutics
2. Pharmaceutical Chemistry
3. Pharmacognosy
4. Pharmacology

II. ELIGIBILITY: To be eligible for admission into the P.G. Degree course in Pharmacy in above specializations, one must have passed 4 year Bachelor Degree Course in Pharmacy (B.Pharm) securing not less than 60% marks from C.S.J.M. University or any other statutory University, recognized as equivalent thereto by this University.

The post-graduate student in the faculty of Pharmaceutical Sciences will not be permitted to register his/her name simultaneously for Diploma or Degree Course of C.S.J.M. University or any other College / Institution.

III. FEES: The Fees and deposits shall be as prescribed by the competent Authority of University

IV. ADMISSION: The Admission to M.Pharm course will be made on the basis of merit cum Interview with equal weightage of marks obtained in overall B.Pharm examination and Interview conducted. Preference will be given to the GPAT/GATE qualified candidates; however this will be the responsibility of candidate to inform the University for his/her GPAT/GATE qualification. The University will not hold any liability for financial assistance/ scholarship for such candidates.

A student, on payment of the prescribed fee, as approved by the University may be entitled for admission into four semesters M. Pharm course.

V. DURATION: The duration of M. Pharm: Course is of two years consisting of four semesters. Each semester is of six months duration. A candidate can be allowed to pass the course for a maximum duration of four years only failing to which he/she will not be allowed to continue.

VI. GRANT OF TERMS: The candidate will be granted a term provided he/she has satisfactorily completed the prescribed course of study & has kept 75% attendance for theory & practical (wherever applicable) separately for each subject. Similarly the student will have to keep 75% attendance for guest Lectures, Seminars, Group Discussion etc.

The examination shall be held at C.S.J.M. University only with the Date, Time and Venue as fixed by the University.

VII. SCHEME OF TEACHING AND EXAMINATION: The scheme of Teaching and Examination for M. Pharm. First, Second, Third and Fourth Semester shall be as follows:

**PROGRAMME OF STUDY AND EXAMINATION FOR TWO YEAR FULL TIME POST GRADUATE DEGREE
COURSE IN PHARMACY [M.PHARM]**

The P.G. degree course in Pharmacy (M.Pharm) shall be a four semester full time Course with each semester having duration of six months with a minimum of 90 working days. The M. Pharm Course shall have the following specializations: (i) Pharmaceutics, (ii) Pharmaceutical Chemistry, (iii) Pharmacognosy and (iv) Pharmacology.

M.PHARM FIRST SEMESTER

Paper No.	Subjects	Theory					Laboratory				
		Teaching Hours/Week	Exam. Hours	Marks			Laboratory Hours/Week	Exam. Hours	Marks		
				Int.	Ext.	Total			Int.	Ext.	Total
M.PH - 101	Advanced Analytical Techniques	3	3	20	80	100	6	6	20	80	100
M.PH - 102	Pharmaceutical Biostatistics & Computer Application	3	3	20	80	100	--	--	--	--	--
M.PH - 103	Drug Regulatory Affairs and IPR	3	3	20	80	100	--	--	--	--	--
M.PH - 104	Respective Major Paper – I	3	3	20	80	100	6	6	20	80	100
Grand Total in 1 st Semester (Theory + Laboratory) = 600											

M.PHARM SECOND SEMESTER

Paper No.	Subjects	Theory					Laboratory				
		Teaching Hours/Week	Exam. Hours	Marks			Laboratory Hours/Week	Exam. Hours	Marks		
				Int.	Ext.	Total			Int.	Ext.	Total
M.PH - 201	Research Methodology in Pharmaceutical Sciences	3	3	20	80	100	--	--	--	--	--
M.PH - 202	Respective Major Paper – II	3	3	20	80	100	6	6	20	80	100
M.PH - 203	Respective Major Paper – III	3	3	20	80	100	6	6	20	80	100
M.PH - 204	Respective Major Paper – IV	3	3	20	80	100	6	6	20	80	100
Grand Total in 2 nd Semester (Theory + Laboratory) = 700											

M.PHARM THIRD SEMESTER

Paper No.	SUBJECTS: Project and Dissertation Work	Marks
M.PH - 301	Synopsis of Proposed Research Work	100
M.PH - 302	Mid Project Seminar	200
		Grand Total in 3 rd Semester = 300

M.PHARM FOURTH SEMESTER

Paper No.	SUBJECTS: Project and Dissertation Work	Marks
M.PH - 401	Thesis on Research Work	200
M.PH - 402	Viva Voce / Project Seminar	300
		Grand Total in 3 rd Semester = 500

VIII. SEMINAR:

The candidate for M. Pharm. course will have to give seminar in each semester for internal assessment. The topics for the seminar during First, Second, Third Semester & Fourth Semester will be as under:

First Semester: Seminar topics to be selected from the papers of specialization.

Second Semester: Seminar topics to be selected from the papers of specialization.

Third Semester: Seminar on the introduction of Thesis.

Fourth Semester: Seminar will be on entire work of Thesis.

The third and fourth semester internal seminars will commence before the Mid project seminar and thesis submission in third and fourth semester respectively.

The duration of the seminar will be about 1 hour. The candidate will have to give seminar with the help of audio visual aids.

Assessment of Seminar: Seminar will be evaluated by two recognized Post-graduate teachers of the subject of specialization, ordinarily one of whom will be the guide of the student. The two examiners will jointly award grade for the seminar as follows:

Grade 'O': 80% or more marks.

Grade 'A': 60% and above but less than 80%.

Grade 'B': 50% and above but less than 60%.

The candidate securing less than 50 % marks is treated as failed. If the candidate fails to secure minimum 'B' Grade in the seminar, he/she will have to give the seminar in the next semester. The grade secured by the candidate in the seminar will be communicated to the University for showing in the statement of marks of the concerned semester.

IX. THESIS:

The topics for the Thesis shall be assigned by the Guide, a recognized Post-graduate Teacher, within one month of the beginning of second semester. Every candidate presenting himself/herself for the M. Pharm. fourth semester examination is required to submit four typewritten copies of the Thesis duly certified by the Guide. Out of four copies of Thesis, one copy is to be submitted in the Institute Library. The Thesis also needs to be certified by the Head / Director of University Institute of Pharmacy. The Thesis is to be submitted not before 23 months from the date of commencement of first term of M. Pharm Course. If candidate fails to submit his/her Thesis within 25 months, he/she will have to submit Thesis in subsequent semester. The Director / Head of University Institute of Pharmacy will forward the Thesis to the University office.

There shall be not more than six submissions of Thesis in one academic year under each fulltime recognized PG guide. Fulltime recognized PG Teacher/Guide from other institute can act only as a co-guide, however the Vice-chancellor can appoint a person to act as Guide to whom he/she consider suitable. If the subject of Thesis entails collaboration with other departments or specialties, the collaborative portion of the work will be supervised by Co-Guide, designated by the University Institute

of Pharmacy in consultation with the Guide. Where a Co-Guide is involved, the Thesis will be certified jointly by the Guide & Co-guide. The Guide or any other Recognized Post-graduate teacher in the subject (Internal Examiner) and an External Examiner appointed by the University will examine the Thesis. The Examiners will jointly assign the marks for Thesis out of 500 (including viva-voce of 300 marks). The allotment of marks of the Thesis shall be as under.

1. Reference Work 30
2. Experimental Work 60
3. Scientific contents 40
4. Presentation/Communication 20
5. Result/Conclusion 50

200 marks

The candidates will be allowed to undertake his/her project work for thesis in any UGC / C.S.I.R. / DRDO / ICAR / ICMR institutions, National Laboratory, State Govt. research organizations, OR such other recognized institutions having sufficient research facilities to carry out intended project work. In such case a Co-Guide as above shall be designated to supervise the work of candidate, from among the Faculty / Scientists of institute / laboratory where the candidate is undertaking his/her thesis project. The Co-Guide will forward the progress report of candidate and certify his/her presence to the Head, University Institute of Pharmacy through the University Guide.

X. VIVA-VOCE:

The candidates will have to appear for Viva-Voce on Thesis. This test will be of 300 marks. The student will have to defend the Thesis. The examiners will jointly assign the marks for Viva-voce. The allotment of marks for Viva-voce shall be as under:

1. Scientific contents 90
2. Presentation/Communication 90
3. Discussion & Defense 120

300 marks

XI. STANDARDS OF PASSING:

A candidate for the degree of Master of Pharmacy will have to pass M. Pharm. First Semester, M. Pharm. Second Semester M. Pharm. Third Semester and Fourth Semester Examination, after keeping terms as laid down.

To pass M. Pharm. First Semester as well as Second Semester Examination, the candidate must obtain minimum 50% marks separately in theory and in practical (including internal assessment), provided he/she must obtain minimum 40 % marks in University theory examination & 50 % in practical examination. Further, the candidate must secure minimum 'B' Grade in the seminars of First, Second & Third Semesters.

To pass M. Pharm. Fourth Semester Examination, candidate must obtain 50% of the total marks for Thesis and Viva-voce on Thesis i.e. the candidate must secure at least 50% marks in Thesis evaluated jointly by internal and external examiner for Viva-voce on Thesis.

XII. INTERNAL ASSESSMENT (In Semester Evaluation):

1. The marks allotted for in-semester evaluation (20%) in each theory paper shall be based on the sessional examinations to be held during the session. There shall be two sessional exams for each theory paper as per schedule of each semester and average of two will be considered for the award of marks. The sessional examination may be held in the form of quiz
2. Each sessional examination shall be of one hour duration and be conducted by the concerned teacher(s) of each paper. The setting of question paper, invigilation duty, evaluation of answer scripts for each paper shall be done by the concerned teacher(s) as a part of his/her/their normal duty. The teacher concerned shall fix the date of the sessional examination in each paper. The students shall write the answers in proper University answer books.
3. After evaluation, the answer scripts should be shown to the students and corrections should be made if necessary. After this, the answer scripts should be collected back from the students. The entire process of evaluation of sessional examination should not take more than two weeks from the date of examination.
4. There shall be no provision for repeat or betterment in the sessional examination. If a student misses any sessional examination for unavoidable reasons, then the concerned teacher may allow the student a separate examination at his/her discretion.
5. If a paper is taught by more than one teacher, then the concerned teachers shall cooperate in conducting the internal evaluation. Each sessional examination of a particular paper shall be of one hour duration even if more than one teacher teaches it.
6. In practical papers sessional assessment will be based on the performance in the day-to-day Laboratory class work including laboratory record and viva-voce.
7. At the end of the semester (Preferably before the end semester examinations begin) the concerned teacher(s) shall submit the in-semester marks in proper mark sheets along with the answer scripts to the Head of the Department. The Head of the Department will take necessary steps to scrutinize and tabulate the marks in the prescribed format with the help of two teachers recommended by DMC. Head of the Department will then send the tabulated marks to the Registrar/controller Department will then send the tabulated marks to the controller of Examinations along with the answer scripts as early as possible.

XIII. CARRYOVER SYSTEM: A candidate who satisfies the requirements of clause XI will be required to appear in those theory papers/ practicals in which he/she failed in subsequent examinations of the same semester.

Marks obtained in a subject in carryover examination shall replace the original marks of the same subject.

XIV. EX-STUDENTSHIP: A candidate opting for ex-studentship shall be required to appear in all theory & practical subjects in the end semester examinations of both semesters of the same academic year. However, the marks pertaining to sessional (in semester evaluation) shall remain same as those secured earlier.

A candidate opting for ex-studentship shall be required to apply to the Institute by paying only examination fee within 30 days from the start of new session.

XV. RE-ADMISSION IN THE INSTITUTE: A candidate shall be allowed for re-admission provided he/she satisfies one of the following conditions:

- a)* A candidate is declared fail.
- b)* A candidate did not appear in a semester examination and/ or he/she was granted permission for not to appear in the examination.
- c)* A candidate has been detained by the institute and has also been permitted to take re-admission.
- d)* A candidate as an ex-student passed the examination of the academic year or qualified for carryover system.
- e)* A candidate promoted with carry over subjects and he/she opted for re-admission.

XVI. RESULT & AWARD OF DIVISION:

- a. The result of a candidate shall be declared for each of the semester separately. However the result of third and fourth semester examinations shall be declared on the basis of combined results at end of final semester.
- b. The final result and award of division shall be based on the average of total marks obtained in all semesters.
- c. If a candidate passes all the examination and secures 50% or more marks but less than 60% marks of the Grand total, he/she shall be placed in **SECOND DIVISION**.
- d. If a candidate passes all the examinations and secures 60% or more marks of the Grand total, he/she shall be placed in **FIRST DIVISION**.
- e. If a candidate passes all the examination in single attempt and secures 75% or more marks of the Grand Total, he/she shall be placed in **FIRST DIVISION WITH HONOURS**.

XVII. AWARD OF RANK: On the basis of final year examination result, the top ten candidates shall be awarded rank according to their merit provided they pass all the examinations in single attempt.

XVIII. UNFAIR MEANS: Cases of unfair means shall be dealt as per the rules of the University and the U.P. Public Examination (Prevention of Unfair means) Act if any in prevalence.

XIX. CANCELLATION OF ADMISSION: The admission of a student at any stage of study shall be cancelled if:

(i) He/She is not found qualified as per State Government norms and guideline or the eligibility criteria prescribed by the University.

Or

(ii) He/ She is found unable to complete the course within the stipulated period as prescribed in clause (4.3)

Or

(iii) He/ She is found involved in creating indiscipline in the institution/ College or in the University.

XX. The Academic Council shall have the power to relax any provision provided in the Ordinance in any specific matter/ situation subject to the approval of Executive Council of the University & such decision(s) shall be reported to the Honorable Vice-Chancellor of the University.

XXI. The details of papers and the distribution of maximum marks for the respective courses in each academic session shall be as indicated as given in the syllabus & study & evaluation scheme.

The ordinance and regulations are subject to modification as decided by the Board of Studies in time to time and subsequent approval from Academic Council of the University.

SYLLABI FOR M.PHARM COURSE

FIRST SEMESTER:

M.PH – 101: Advanced Analytical Techniques (Theory)

1. Spectroscopic methods:

Theory, Instrumentations, chemical applications and structural elucidation by UV, IR, ¹H NMR, ¹³C NMR including DEPT, Mass Spectrometry, ESR and Emission spectroscopy.

2. Separation techniques:

Fundamental principles, theory, instrumentation and application of Gas-liquid chromatography, HPLC, Size Exclusion chromatography, GC-MS, LC-MS, UPLC, HPTLC, Ion Pair & Ion Exchange Chromatography and Supercritical Fluid Chromatography.

3. Thermal Analysis:

Theory, Instrumentations and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA).

4. Calorimetric Analysis: Theory, Instrumentations, chemical applications and structural Elucidation, Differential Scanning Calorimetry (DSC), Isothermal titration Calorimetry (ITC)

5. Powder X-ray Diffraction: Instrumentation and applications.

M.PH – 101P: Advanced Analytical Techniques (Laboratory)

1. Combination Drug Analysis (Any Five): Vitamins, Oral antidiabetics, NSAIDs, Antimicrobials, Antihistamines, Antihypertensive
2. Illustrations of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectro-photometric (including flame photometric) methods, HPLC etc. The titrimetric methods should include argentometric, conductometric, and potentiometric end-point determination.
3. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.
4. Interpretation of UV and IR spectra of some unknown intermediates and drugs. (Any two)

M.PH – 102: Pharmaceutical Biostatistics and Computer Application:

1. Methods of collection of data, classifications and graphical representation of data. Binomial and normal probability distribution. Polygon, histogram, measure of central tendency. Significance of statistical methods, probability, degree of freedom, measures of variation - Standard deviation, Standard error.
2. Sampling, sample size and power. Statistical inference and hypothesis. Tests for statistical significance: student t-test, Chi-square test, confidence level, Null hypothesis.
3. Linear regression and correlation. Analysis of Variance (one way and two way). Factorial designs (including fraction factorial design). Theory of probability, Permutation and Combination, Ratios, Percentage and Proportion. Two way ANOVA and Multiple comparison procedures.
4. Non-parametric tests, Experimental design in clinical trials, Statistical quality control, Validation, Optimization techniques and Screening design. Correlation and regression, least square method, significance of coefficient of correlation, nonlinear regression.
5. Bioassays-calculations of doses response relationships, LD_{50} , ED_{50} , probit analysis.
6. Applications of software for statistical calculation viz. SPSS, foxtron.
7. Application of computers in Pharmaceutical sciences.

MPH-103: Drug Regulatory Affairs and Intellectual Property Rights

1. Drug & Cosmetics Act with special reference to schedule Y and M, schedule of medical devices.
2. Concept of total quality management, requirements of GMP, GLP, GCP, Regulatory requirements of drugs and Pharmaceutical (USFD-NDA/ ANDA)
3. Documentation and Maintenance of records.
4. Intellectual property rights patents, Trademarks, Copyrights, Patents Act.
5. Environment protection Act, Pollution Control Acts, Factories Act.
6. Material Safety Data Sheet (MSDS) preparation

MPH-104: (a) Pharmaceutics Major – 1: Advanced Pharmaceutics (Theory)

1. PREFORMULATION:- Introduction and concept, Need, Advantages, Organization. Preformulation Techniques:- Solubility & pKa, Spectroscopy, Chromatography, Thermal Analysis, X-ray diffraction:- Techniques to generate & characterize amorphous & crystalline forms. Stability. Brief account of preformulation of i) Conventional tablet - Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; Effect of particle size, moisture content, lubrication, lubricant sensitivity ii) Oral liquids, Suspension, iii) Semisolid, iv) Aerosol products.
2. POLYMER SCIENCES:- Introduction and classification, preparation methods of synthetic polymers, Molecular weight determination, Thermal characterization and rheology of polymers. Introduction to biodegradable & biodegradable polymers.
3. STABILITY:- Concept of stability of pharmaceuticals. Understanding of statistical aspects in expiry period. Degradation pathways, Physical instabilities & evaluation methods. Overages and ICH guidelines.
4. EXCIPIENTS:- Overview of excipients used in formulations. Factors affecting the selection. Introductory aspects of drug-excipient and excipient, package interactions. Study of newer excipients like cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants- micelle formation, liquid crystal phase, thickeners. Standardization of excipients.
5. QUALITY ASSUARANCE:- Concept of quality control, quality assurance & total quality controls. Sources of variation, Quality control of raw materials & pharmaceutical process & finished products. Documentation concepts of statistical quality control. Validation of pharmaceutical process (at least one case study of a process & analytical method.)
6. DIFFUSION & DISSOLUTION:- Concept and importance of dissolution. Steady state diffusion. Determination of diffusion coefficient & its importance. Concept & importance of dissolution. Dissolution test, Historical development & USP dissolution test. Dissolution model like Hixson-Crowell, Higuchi's Model. Drug release modeling through polymer matrix & laminates. Concept of membrane controlled delivery & its importance in dosage form design.

7. MICRO ENCAPSULATION:- Theory, methods, applications, kinetics of release of drugs from microcapsules, formulations and evaluation.
8. OPTIMIZATION:- Definition, need, advantages, Meaning of general terms involved in optimization process. Classification of optimization methods. Brief description and importance of experimental design with special reference to designs adequate for large number of variables. Introduction of correlation & regression analysis & mathematical model, contour plots. Basic understanding with at least one example of following optimization techniques:- Simplex method, langarengian method, EVOP, Grid search method.

MPH-104 P: (a) Pharmaceutics Major – 1 (Laboratory):

1. Preformulation study of tablets, Compressibility index, Heckle treatment, Kawakita plots.
2. Determination of the order of decomposition for drugs like Aspirin, Benzocaine, Acetanilide or any other three drugs
3. To develop and validate the UV spectroscopic analytical method of any one drug
4. To develop and validate the analytical method of any one drug using high performance liquid chromatography
5. To determine the aqueous solubility of given drug sample at various temperature and report its thermodynamic parameters.
6. To study the effect of pH (2,4,6.2 and 8.0) on the apparent partition coefficient of a drug in n-octanol- water buffer system.
7. To determine the best compatible additive for aspirin tablets using at least five known tablet components.
8. To study the effect of copper ions on the ascorbic acid stability in solution
9. Rheological and thermal Characterization of polymers.

MPH-104 (b) Pharmaceutical Chemistry Major – 1:

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

2. Stereochemistry & Chiral Techniques:

- i.* Principles of stereochemistry including geometric isomerism, optical isomerism and conformational isomerism, Dynamic stereochemistry.
- ii.* Concept of chiral drugs, resolution of racemic mixtures, racemic switches, asymmetric synthesis of the following drugs: Vitamin C, Propranolol, Nifedipine, Atenolol, Ethambutol, Penicillamine, Omeprazole, Aspartame, Ampicillin, and Thalidomide.
- iii.* Role of stereochemistry in Pharmacokinetics and Pharmacodynamics

5. Mechanisms, stereochemistry and applications of following individual reactions:

1. Hydrogenation
2. Reduction with metallic hydrides
3. Clemensen Reduction
4. Wolf Kishner reduction
5. Birch Reduction
6. Meerwein-Ponndorf reduction
7. Oppenauer oxidation
8. Free radical reaction
9. Allylic Bromination
10. Use of diazomethane and peracids in synthesis
11. Grignard Reaction
12. Pinacol and related rearrangements
13. Beckmann rearrangement and ozonolysis
14. Heck reaction
15. Sharpless oxidation
16. Suzuki coupling
17. Wittig Reaction

4. Synthone approach: Definition, terms and abbreviation, rules and guidelines used in synthesis of following drugs: Rosiglitazone, Trimethoprim, Terfenadine, Ibuprofen, Fentanyl, Midazolam, Ciprofloxacin, Captopril, Diclofenac, Losartan

- 5. Solid phase Chemistry:** Reaction involved with mechanism, which include protection, de-protection, and coupling.
- 6. Green Chemistry:** Water as solvent, ionic liquids, supercritical liquids, Supported reagents and catalysts, Solvent free reactions, activation by Microwave, Ultrasound etc.

MPH-104P (b) Pharmaceutical Chemistry Major – 1 (Laboratory):

1. Experimental techniques – Fractional distillation, Vacuum distillation, Preparative chromatography- Column and TLC.
2. Synthesis of any five different heterocyclic compounds using reactions discussed under point 2 of theory syllabus.
3. Practical illustrations of any five reactions described in the point(2) of theory syllabus.
4. Principles, mechanism and techniques of stereo controlled synthesis of Nifedipine, Chloroxazone and Paracetamol.
5. Isolation of phytochemical principles (e.g. alkaloids, steroids) from natural origin.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

MPH-104 (c) Pharmacognosy Major – 1

1. ***Biogenesis of secondary metabolites:*** Application of tracer techniques in evaluation of biogenetic pathways of secondary metabolites.
2. Strategies to enhance secondary metabolite production through tissue culture techniques like-precursor feeding, elicitation, genetic manipulation, bioreactor techniques, biotransformation, etc.
3. ***Chemotaxonomy of medicinal plants:*** Introduction, principle of Chemotaxonomy, Role of secondary metabolites in chemotaxonomy, applications of chemotaxonomy in medical botany. 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.
4. ***Natural Product Drug Discovery & Comparative Phytochemistry:*** Introduction, methods involved, recent advances and developments, Relationship between Phytochemistry and Taxonomy. Comparative Phytochemistry of alkaloids, flavonoids and C-glycosides.
5. ***Natural products*** used as colour pigments, excipients, biopolymers, photosensitizing agents, flavours, biofuels
6. ***Recent advances in Pharmacognosy:*** With special reference to anticancer, antidiabetic, hepatoprotective, anti-inflammatory, hypo lipidaemic, immunomodulatory drugs.
7. Plant tissue culture: Basic principles, Technological advances & application in Pharmacy.

MPH-104P: (c) Pharmacognosy Major – 1 (Laboratory):

Preparation of monograph (Min.10) of herbal drugs by considering the following parameters.

1. Pharmacognostic study of crude drugs: morphology, microscopy, quantitative microscopy, chemical tests etc.
2. Extraction, fractionation, proximate chemical analysis.
3. Physical parameters of evaluation: Moisture content, ash values, extractive values etc.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

MPH-104 (d) Pharmacology Major – 1:

- 1. 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.
- 2. Care, handling and breeding techniques of laboratory animals.** Regulations for laboratory animal care and ethical requirements. Knowledge of CPCSEA Performa for performing experiments on animals. Alternatives to animal studies.
- 3. Organization of Preclinical screening** programme and safety assessment tests.
- 4. In - Depth Knowledge of Preclinical evaluation** of following category of drugs:
 - a. Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotic, nootropics, antiparkinsonian agents, analgesics, antipyretics
 - b. Anti-inflammatory agents, anticonvulsants, local anesthetics, CNS stimulants
 - c. Cardiac glycosides, anti-arrhythmic, antihypertensives, anti-atherosclerotic
 - d. Anti ulcer agents, laxatives
 - e. Bronchodilators, antitussives
 - f. Diuretics
 - g. Histamine antagonists
 - h. Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics.
 - i. Hypoglycemic, anti fertility agents, androgens
 - j. Anti- thyroid agents
- 5. *In vitro* testing of Drugs:** Animal cell lines and their uses, limitations of *in vitro* testing of drugs.
- 6. Knowledge of Modern Methods of Pharmacological evaluations** including radioligand binding assay, patch clamp, ELISA, and other sophisticated methods
- 7. Evaluation of toxicity:**
 - a. Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinetics, mutagenesis and carcinogenesis.
 - b. Behavioral, Inhalation, cellular and sub-cellular toxicity, acute, sub-acute and chronic toxicity studies according to guidelines.
 - c. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, FHSA, EPA, EEC, WHO etc.

MPH-104P (d) Pharmacology Major – 1 (Laboratory):

1. Introduction to Pharmacological evaluation methods and CPCSEA and OECD guidelines, GLP norms
2. Normal biochemical reference values in various animal species.
3. Standard techniques for injection of drugs, collection of blood samples and feeding of animals
4. Study of various techniques of anesthesia and euthanasia
5. Computer simulation of following animal experiments through soft wares such as X-pharm and X-cology
 - a. Study of mydratic and miotic effects of the drugs
 - b. Study of various drugs on dog Blood pressure
6. Screening of antiulcer agents
7. Evaluation of local anesthetics,
8. Evauation of anticonvulsant agents

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

SECOND SEMESTER:

M.PH – 201: Research Methodology in Pharmaceutical Sciences:

Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research

1. Literature survey: Use of Library, books & journals-Medlines-Internet, gating patients & reprints of articles as a source for Literature survey.
2. Selecting a problem & preparing Research proposals for different of Research mention above
3. Methods & tools use in research –
 - a) Qualities studies, quantitative studies
 - b) Simple data organization descriptive data analysis,
 - c) Limitation & sources of Error
 - d) Inquiries in form of Questionnaire, Opinionnaire or by Interview
 - e) Statistical analysis of data including variance, standard deviation, student “ t” test, ANOVA, correlation data & its interpretation
4. Documentation: “How” & “What” of documentation, Techniques of documentation, Importance of documentation, Uses of Computer packages in documentation.
5. The Research Report Paper writing/ thesis writing, Different parts of the Research paper
 - a) Title –Title of project with authors name
 - b) Abstract- Statement of the problem, Background list in brief and purpose and scope.
 - c) Key Words.
 - d) Methodology - subject, apparatus, instrumentation & procedure.
 - e) Results- tables, graphs, figures & statistical presentation
 - f) Discussion support or non support of hypothesis, practical & theoretical implications
 - g) Conclusion
 - h) Acknowledgements.
 - i) References
 - j) Errata
 - k) Importance of Spell check for entire project
 - l) Uses of footnotes

6. **Presentation** (Specially for oral): Importance, types different skills, contained, format of model, introduction & ending, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire
7. **Protection of patents & trade marks designs & copyrights:** The patents system in India, present status intellectual property rights. Advantages, The Science in law, Qurimetrics (Introduction) What may be patented, who may apply for patents, Preparation of patent proposal registration of patents in foreign countries & vice versa. Cost analysis of the project – cost incurred on raw materials, Procedure, instrumentations & clinical trials. Sources for procurement research grants. Industrial-institution interaction- Industrial projects, their, feasibility reports.
8. **Computer and Software applications:** use of Computers and software including M.S. word, M.S. excel, PowerPoint, SPSS, Graphtec, Prism, Disso, Expharm, and other advanced software available in time, useful for pharmaceutical Sciences.

M.PH – 202 (a): Pharmaceutics Major – II:

- 1. PACKAGING OF PHARMACEUTICALS:** Science of Packaging, Regulatory perspective of selection and evaluation of Pharmaceutical packaging materials. 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.
- 2. PRODUCTION AND PLANNING MANAGEMENT:** Space Allocation, environmental factors, Manufacturing, Materials, Management, Sales forecasting, Cost Control. Material Handling, Blending, Granulation, Drying, Slugging Compression, Coating liquid Dosage Forms Contract Manufacturing.
- 3. QUALITY CONTROL PROCESS AND DOSAGE FORMS:** Process control: Control of manufacturing process, statistical quality control, control charts, automated process control, Testing programme and method, product identification system, Adulteration and misbranding, Drug information profile. Validation: Regulatory basis, validation of solid dosage forms, Sterile products, Liquid dosage forms. Process validation of raw materials, Validation of analytical methods, Equipment, and process.
- 4. PILOT PLANT SCALE UP TECHNIQUES:** Introduction, need, Effect of scale up on formulation, process parameters like mixing, granulation, drying, compression, coating, packaging, stability, selection and evaluation of suitable equipments.
- 5. FORMULATION DEVELOPMENT:** Pharmaceutical preparations. Formulation development functions; stages in formulation development; preformulation testing, preformulation trails. Data required for formulation development, formulation factors; Stability and stabilisation, preservatives, Organoleptic properties and product appeal, packaging, evaluation of raw materials, aspects of Labeling and Container design, Documentation, protocols, forms and maintenance of records in formulation development department.
- 6. EVALUATION OF PHARMACEUTICAL FORMULATIONS:** Pharmacopoeial characterization and Evaluation of dosage forms, Drug release study: *in vitro* and *in vivo* studies and their correlation. Levels and types of *IV-IVC*. Surface topography of solid dosage forms, Drug – drug and drug-excipient interaction, rheological characterization, permeability and absorption characterization, drug protein binding, Techniques: AFM, SEM, TEM, XRD, DSC, DTA/TGA, Electrochemical Analysis, Dynamic contact angle etc

M.PH – 202P (a): Pharmaceutics Major – II (Laboratory):

1. Analysis of glass as packaging material, testing of rubber closure and containers, leak test of sealed ampoules.
2. Test for sterility, sterile processing. Test of preservatives like phenol/ thiomersal in vaccines.
3. Solubility, solubility plots, and advanced methods of characterization of solubility and permeability, CACO-2 cells, understanding the utility of BCS in oral drug delivery technology.
4. Study of different types of packaging and labeling of pharmaceuticals.
5. Interpretation of data from (at least five) SEM, TEM, DSC, XRD etc
6. Mathematical modeling of drug release, diffusion and protein binding, effect of protein binding on drug absorption.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 203 (a): Pharmaceutics Major – III:

1. ADVANCES IN SOLID DOSAGE FORMS: Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, physics of tablet compression. Basics of process automation of solid dosage form production. Study of newer excipients used in Gastro retentive Drug Delivery Systems, Mucoadhesive Systems, and Colon specific Drug Delivery Systems and sustained release Drug Delivery Systems, pulsatile drug delivery systems. Formulation development of mouth dissolving and fast release tablets, floating tablets, taste masking formulation, sublingual and buccal formulations
2. LIQUIDS AND SEMISOLID DOSAGE FORMS: Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and emulsions including multiple emulsion, micro emulsion, Self Emulsified Drug Delivery Systems and Self Micro Emulsified Drug Delivery Systems. Semisolid formulation, drug delivery gels, methods of modifying drug release with special reference to penetration enhancers. Emulgels, semisolids based on Liposomes, Niosomes.
3. POWDERS, SOFTGELS & DERMATOLOGICAL PRODUCTS: Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms. Large scale manufacturing technology of soft capsules, optimization of production and quality assurance. Rheological behaviour of dermatological vehicle, correlation of rheological parameters with drug bioavailability. Transdermal drug delivery systems.
4. INHALATION AEROSOLS: Inhalation products- Types and clinical role. Basic components of aerosol formulations. Therapeutic aerosols, Metered Dose Inhalers, Dry powder inhalers etc. Detailed discussion on propellants, package and filling technology. Quality assurance of components and formulations
5. PARENTERAL MEDICATIONS: Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Parenteral admixtures and incompatibilities, Aseptic Processing Operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.
6. NANOPHARMACEUTICALS: Solid submicron drug delivery systems, Generation and significance of Nano-Pharmaceuticals like nanosuspensions, nanoemulsions, nanogels, nanocarrier systems, nanorobots, phytosomes, functional nanostructures, and Bioelectronics.

M.PH – 203P (a): Pharmaceutics Major – III (Laboratory):

1. Preparation and characterization of at least 10 dosage forms of above categories.
2. Bloom strength of gelatin,
3. Base absorption and m/g factor
4. Creep analysis,
5. Different tests for mucoadhesion,
6. Experiments demonstrating pH sensitive drug release.
7. Testing of materials and products related to the dosage form design.
8. Preparation of liposomes, nanoparticles etc.
9. Study of the floating time
10. Study of formulation and process parameters

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 204 (a): Pharmaceutics Major - IV:

1. BIO-PHARMACEUTICAL & PHARMACOKINETIC ASPECTS:

Introduction, definition, factors related to formulation, dosage form, manufacturing process, stability, storage, different testing parameters and standards as per regulatory requirements of European community, united states, Indian and other regulatory authorities. Preclinical aspects of biopharmaceutics, clinical bioavailability, study design, presentation, documentation, statistical analysis, current guidelines and developments as per regulatory requirements of European community, united states, Japanese, Indian and other regulatory authorities. Introduction, regulatory requirements, pharmacokinetics in men, ethnic, genetic and environmental factors. Clinical study design, documentation, presentation and interpretation. Clinical trials: definition, phase I, Phase II, Phase III, and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data, factorial design, guidelines as per European community, united states, Japanese, Indian and other regulatory authorities.

2. CONTROLLED DRUG DELIVERY SYSTEM: Fundamentals, Theory of mass transfer, use of polymers in controlled drug delivery, pharmacokinetic and Pharmacodynamic basis of controlled drug delivery. Aspects of disease condition on drug delivery manipulation. Design, fabrication, evaluation, applications and latest technological advancements of the following controlled release systems.

- a. Controlled release oral drug delivery systems.
- b. Parenteral controlled release drug delivery systems
- c. Implantable therapeutic systems.
- d. Transdermal therapeutic systems and iontophoresis.
- e. Ocular and intrauterine delivery systems.
- f. Bioadhesive drug delivery systems.
- g. Proteins and peptide drug delivery.

3. DRUG TARGETING APPROACHES: General introduction, concepts and approaches. Active and passive targeting. Tumor targeting, Bone marrow targeting. Brain targeting, organ targeting. Fundamentals, rationale, preparation, applications, merits, demerits, recent technological advances and further prospects of drug targeting with greater emphasis on following approaches of drug targeting.

- a. Physical-mechanical approaches of drug targeting: Biodegradable polymers, micro-needles, osmotic pumps, polymeric inserts, micro and nanoparticulate devices, thermosensitive, pH-sensitive, vesicles, sonically driven targeted drug delivery, and others.
- b. Biological Approaches of drug targeting: Monoclonal antibodies, resealed erythrocytes, lipoproteins, hormones, antibody-drug conjugates, limitations of antibody targeting, drug loading, biodistribution of antibody.
- c. Chemical Approaches of Drug targeting: Target mediated targeting, prodrug approaches, Covalent complexes etc.
- d. Retrometabolic drug targeting approaches: Soft drugs, inactive metabolic approaches, activated soft compounds, controlled release of endogenous soft compounds, active and inactive metabolic approaches of targeting.
- e. Bioelectronics and magnetic targeting: Magnetic microspheres, microchips, iontophoretic devices and other latest developments.

4. DELIVERY OF VACCINES/PEPTIDES/PROTEINS/BIOTECHNOLOGY DRUGS: FORMULATION ASPECTS: Preformulation studies and problems: Protectants, delivery kinetics. Overview of delivery systems, Site specific proteins, Stability problems, Evaluation of recombinant proteins. Evidence and mechanism of uptake and transport, Monoclonal antibodies, Delivery systems used to promote uptake, Absorption enhancers, Lipid carrier systems, Oral immunization, Peyer's patches, Common mucosal immune system, Controlled release microparticles for vaccine development, Single dose vaccine delivery systems using biodegradable polymers.
5. ADVANCES IN THE MONITORING OF PHARMACOTHERAPEUTICS AND IN DRUG DELIVERY SYSTEM DESIGN.

M.PH – 204P (a): Pharmaceutics Major – IV (Laboratory):

1. Calculation of pharmacokinetic parameters, pH-partition theory, compartmental modeling, drug metabolism and interaction experiments.
2. Preparation and evaluation of microspheres by different methods, transdermal patches, bioadhesive drug delivery systems.
3. Experiments involving drug targeting. Permeation enhancement.
4. More experiments based on theory as may be designed by the subject teacher.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 202 (b): Pharmaceutical Chemistry Major - II:

1. **Genesis of New Drugs:** Source, random screening, leads from natural products, molecular modifications, prodrug and soft drug concepts.
2. **Theoretical aspects of drug design:** Structural features and pharmacological activity, significances of various types of isomerism with respect to pharmacological activity, concept of isosterism.
3. **Microorganism in drug development:** Microbial conversions of drugs like steroids, prostaglandins and antibiotics. These should include some biotechnology-oriented chapters like enzymes immobilization techniques.
4. **Molecular concept of drug receptor interactions.** Advances in following classes of receptors and their drug ligands, Opioid, Dopamine, Adrenergic, Cholinergic, Histamine, 5-HT_{1A}, GABA.
5. **Combinatorial chemistry:** solid phase synthesis, Different types of polymer supports, linkers, Strategies of library synthesis and characterization Solid phase strategies
 - a. General strategies and concepts
 - b. Specific implementation issues
 - i. Solid support
 - ii Anchoring chemistry
 - iii. Coupling chemistry
 - iv. Protection schemes
 - v. Analytical methods
 - c. Solution phase analysis
6. **Brief introduction to QSAR and CADD.**
7. **Psychopharmacological agents:** Classification, mechanism of action, SAR, synthetic approach and recent advances of a) Biochemical basis of mental disorders:- Abnormal protein factors, endogenous amines and related substances, faulty energy metabolism, genetic factors and nutritional disorders; Phenothiazines: chemistry, synthesis and evaluation methods. The

important pharmacological activities of phenothiazines; SAR of phenothiazines, toxicity and clinical significance of phenothiazines. **b)** Antidepressants: MAO inhibitors, tricyclic antidepressants and Miscellaneous compounds. Mechanism of action, clinical and biological uses, side effects and their SAR studies. Synthesis of clinically useful drugs of each of the above classes.

- 8. Chemotherapy of Cancer:** A detailed classification of antineoplastic agents, mechanisms of action, their SAR studies, and synthesis of different classes; Alkylating agents and radiomimetic agents, antimetabolites, sex hormones & analogs, and antibiotics. A mention of natural products used in cancer treatment; Vinca alkaloids (Vincristine and Vinblastine) podophyllum and paclitaxel.
- 9. Drugs Related to Hormones and other autocooids:** A study of the following hormones and other autocooids including classification, mechanism of action, SAR, synthetic approach and recent advances of following with a special reference to their agonists and antagonists:
- a) Peptide Hormones: Insulin, Vasopressin and Oxytocin.
 - b) Histamine (H₁ and H₂) and 5-HT.
 - c) Thyroid Hormones (T₃ and T₄).

10. Radioprotective drugs.

M.PH – 202P (b): Pharmaceutical Chemistry Major – II (Laboratory):

Experiments based on theory

Sufficient number of Experiments has to be conducted not less than 6 hours per week.

M.PH – 203 (b): Pharmaceutical Chemistry Major - III:

1. ALKALOIDS: STUDY OF THE FOLLOWING CLASSES OF ALKALOIDS.

- a) Alkaloids of Opium: Structure elucidation of Morphine, Opioid receptors; Endorphines and Enkephalins; structure activity relationships in morphine molecule; Development of morphine analogues based on SAR; relative potencies; antitussive agents; antidiarrhoeals; morphine antagonists.
- b) Alkaloids of Atropa belladonna ; Atropine, Hyoscyamine and Hyoscine; Structure elucidation of Atropine; Structural considerations of Atropine; Homatropine; Therapeutic uses.
- c) Alkaloids of Vinca rosea ; Vincristine and vinblastine; Structure elucidations; Structural modifications and semisynthetic derivatives.
- d) Alkaloids of Ergot: Classification; Structures; Structure elucidation of Ergometrine; therapeutic uses of ergot alkaloids and derivatives (vinyl and methylsergide).

2. STEROIDS:

- a) Steroid nomenclature, stereochemistry and numbering; New insights on steroid receptors; chemical and physical properties of steroids; changes to modify pharmacokinetic properties of steroids.
- b) Sources and structure elucidation of cholesterol; sources and structures of related steroids – Ergosterol, Stigmasterol, β - sitosterol and Diosgenin.
- c) Steroidal Anti-inflammatory Agents; structures; structure-activity relationships; therapeutic uses.
- d) Steroidal Anti-fertility agents: Structures; mechanism of action; regimen.
- e) Anabolic Steroids: Structures; uses.
- f) Steroids in the treatment of cancers.

3. ANTIBIOTICS:

- a) **Cephalosporins:** Historical background; Nomenclature; Natural and semi- synthetic cephalosporins; cephamycins; classifications; structures; chemical degradations; spectrum of activity; β – Lactamase resistance; Antipseudomonal cephalosporins.

b) **Anticancer Antibiotics: Source**, structure, description of the structural features, mechanism of action, SAR, uses of the following antibiotics.

- i. Actinomycines – Dactinomycin., Anthracyclines – Daunorubicin and Doxorubicin – Their metabolic products: Daunomycinol and Adriamycinol- Their semisynthetic derivatives: the 4'-Deoxy and 4'-epidoxorubicines. Nogalamycin and menogaril.
- ii. Aureolic acid group – Mithramycin
- iii. The Bleomycines, Mitomycins and streptozocin.

4. **A BRIEF ACCOUNT OF THE FOLLOWING:**

- a) **Anticancer Agents of Plant Origin**: Sources and structures of podophyllotoxin, Taxol and camptothecin; their semi synthetic derivatives; their uses and mechanism of action.
- b) **Ginseng**: Historical background; structures of Ginsenosides, protopanaxadiols and triols; uses.
- c) **Phototherapy**: sources and structures of psoralens; Photodegradation of 8 – methoxypsoralen; PUVA therapy in psoriasis and rutiligo; khellin and KUVA therapy xanthotoxin in the treatment of psoriasis.

M.PH – 203 (b): Pharmaceutical Chemistry Major – III Laboratory:

1. **Isolation, purification and characterization of some of the following phytoconstituents:** Piperine from Black pepper, Strychnine and Brucine from Strychnos nuxvomica, Caffeine from Tea powder, Curcumin from Turmeric, Bixin from Bixa orellena, Diosgenin from Dioscorea tubers, Sennosides from Senna, Hesperidin from orange peel, Embelin from Embelia ribes, Glycyrrhizin from Glycyrrhiza glabra, Plumbagin from plumbago rosea, Pectin from orange peel, Tannins from myrobalans,
2. The use of Column chromatography, Flash Chromatography and Vacuum liquid chromatography in the isolation of some of the above mentioned phytoconstituents.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 204 (b): Pharmaceutical Chemistry Major – IV (Polymers and Bio-organic chemistry)

1. Polymers- Science of polymers, classification, in depth synthesis and modifications, reactions, crystallinity, polymer degradation mechanism, copolymerization, grafting and their characterization with physico-chemical and rheological parameters and instrumental analytical techniques. Dynamic mechanical properties of polymers. Glass transition temperatures, glassy polymers, electron microscopy of polymers. Applications in Pharmacy. Polymers in drug discovery.
2. Introduction, classification, chemistry and biological activity, and bio of vitamins.
3. Classification, structural determination, linkages, stereochemistry and biological activity of carbohydrates.
4. Classification, structural determination, linkages, stereochemistry, biological activity of steroids with reference to cholesterol, bile acids, sex hormones, corticoids,(gluco & mineralo-corticoids) cardiac glycosides and saponins.
 1. Introduction to glycoproteins, lipoproteins and glycopeptidolipids.
 2. Fullerenes- Introduction, chemical reactions and applications.
 3. Enzymes-Immobilized enzymes/ cells in organic synthesis.
5. Chemistry of therapeutically important industrial phytoconstituents.

M.PH – 204P (b): Pharmaceutical Chemistry Major – IV Laboratory:

Experiments based on theory including:

1. Polymerization reactions, characterization of Pharmaceutical polymers, both natural synthetic
2. Determination of methyl branches of polyethylene, Rheological characterization.
3. Determination of glass transition temperature
4. Enzyme immobilization
5. More experiments as designed by subject teacher based on contemporary needs.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 202 (c): Pharmacognosy Major – II

1. PHYTOCHEMICAL SCREENING OF CRUDE DRUGS: Extraction, isolation, purification, characterization of following phytoconstituents.
 - Alkaloids**: Caffeine, Atropine, Ergometrine Morphine
 - Glycosides**: Digoxin, Sennosides
 - Flavonoids**: Rutin, Quercetin
 - Terpenoids**: Taxol, Pyrethrin
 - Saponins**: Glycyrrhizic acid, Diosgenin
2. STRUCTURAL ILLUCIDATION: Structural illucidation of above isolated phytoconstituents.
3. STANDARDIZATION OF FOLLOWING PHYTOPHARMACEUTICALS: Standardization of following phytopharmaceuticals by UV, IR, HPLC, and HPTLC, GCMS techniques. Vasicine, Andrographolides, Phylanthin, Solasodine, Gingerol, Bacoside, Curcumin, Lupeol,
4. PHARMACOLOGICAL SCREENING: Brief introduction to Pharmacological Screening Methods with example of following category of medicinal herbs.
 - a) Hepatoprotectives
 - b) Antidaibetics
 - c) Antiepileptics
 - d) Hypolipidaemics
 - e) Antioxidants
 - f) Anti-inflammatory, analgesics.
5. STUDY OF HERBAL EXTRACTS: Processing, equipment and analytical profiles. Sterility, stability and preservation of extracts
6. WHO GUIDELINES FOR ASSESSMENT OF CRUDE DRUGS: Evaluation of identity, purity, and quality of crude drugs. Determination of pesticide residue. Determination of Arsenic and heavy metals. Determination of Micro-organisms.

M.PH – 202P (c): Pharmacognosy Major – II Laboratory:

1. Extraction, isolation, purification and characterization of important phytoconstituents belonging to different classes.
 - a. Eugenol from Clove
 - b. Sennosides from Senna
 - c. Curcumin from Turmeric
 - d. Glycerrhizin from Liquorice
 - e. Hesperidine from Orange Peels
 - f. Caffeine from Tea
 - g. Strychnine and Brucine from Nux Vomica
 - h. Cineole from Eucalyptus
2. Study of UV, Visible, IR Spectral data of some phytoconstituents
3. Study of HPLC and HPLTC (if possible) Techniques for some important phytoconstituents.
4. Antimicrobial screening of plant extracts
5. Screening of drugs for microbial count
6. Experiments based on WHO guidelines of quality control of medicinal plant materials
7. Other Experiments as designed by subject teacher based on theory as per contemporary needs.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 203(c): Pharmacognosy Major – III:

1. ROLE OF MEDICINAL PLANTS IN NATIONAL ECONOMY : Economic growth potential in natural health and cosmetic products. Future economic growth. Development of herbal medicine industry.
2. WORLDWIDE TRADE IN MEDICINAL PLANTS AND DERIVED PRODUCTS: Demand for medicinal plants and herbal medicine. Trends in worldwide trade of Medicinal plants. International trade. Major importing-exporting regions and countries.
3. INDIAN TRADE IN MEDICINAL AND AROMATIC PLANTS: Export potential of Indian medicinal herbs. Indian medicinal plants used in cosmetics and aromatherapy. Spices and their exports.
4. GLOBAL REGULATORY STATUS OF HERBAL MEDICINES: World Health Organisation guide lines for herbal drugs including standards for pesticide residue / aflatoxins. Current status of regulatory affairs for herbal formulations.
5. PATENTS: Indian and international patent laws, Recent amendments as applicable to herbal/ natural products and processes Plant breeders right.
6. TECHNOLOGICAL ASPECTS OF INDUSTRIAL PHARMACOGNOSY: Technology for commercial scale cultivation and processing of following aromatic plants: Lemongrass, Geranium, Basil, Palmarosa, Vetiver, Patchouli, Japanese Mint, Rose, Hops, Clove, Cardamom, Cinnamom Jasmine, Sandal, Dill, Celery, Anise, Davana.
7. PHARMACEUTICAL AIDS: Profile for manufacture and commerce of Papain, Pectin, Pharmaceutical gums, Starch, Absorbent cotton and Gelatin. Recent trends in utilization of vegetable laxatives and vegetable bitters. Natural sweetening agents and coloring agents.
8. CULTIVATION / PRODUCTION ASPECTS: Exogenous and endogenous factors influencing production of crude drugs. Plant growth regulators and their applications in pharmacy. Disease management of medicinal and aromatic plants. Variability in crude drug activity.
9. Endangered species of medicinal plants. Current status of plants used in alternative system of medicines.

M.PH – 203P (c): Pharmacognosy Major – III Laboratory:

1. Phytochemical screening of plant extracts : Preparation of extracts and detection of phytoconstituents by different techniques.
2. Representative exercised based on extraction of pharmaceutical aids and volatile oils listed in theory.
3. Compilation of literature project on topics included in theory.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 204(c): Pharmacognosy Major – IV:

1. INDUSTRIAL ASPECTS OF HERBAL DRUGS: Study of infrastructure for different types of industries involved in making standardized extracts and various dosage forms including traditional ayurvedic dosage forms and modern dosage forms.

Plant based industry and institutions involved in work on medicinal and aromatic plants in india. Classification of medicinal plant based industry. Production and utilization of medicinal plants and their products in India. List of medicinal plants cultivated in India. Technology sources of some Indian medicinal plants.

2. Profiles for commercial cultivation technology/and post-harvest care of following medicinal plants : Ashwagandha, Periwinkle, Medicinal Yams, Ergot, Guggul, Belladonna, Senna, Neem, Papaya, Opium poppy, Psyllium, Steroid bearing Solanums, Ammi majus, Ipecac, Cinchona, Liquorice, Safed Musli, Aloe, Henbane, Digitalis, Saffron.
3. BIOACTIVE COMPOUNDS: Occurrence, Methodology for extraction and chemical nature of sennosides, digoxin, ginsenosides, solasodine, berberine, quinine, scopolamine, atropine, emetine, ergot alkaloids, caffeine, taxol, withanolides, podophyllotoxin, cod-liver oil, shark-liver oil. Hallucinogenic, allergic, teratogenic and other toxic plants. Drugs and Pharmaceuticals from marine source (Marine Pharmacognosy) with special reference to cardiovascular, cytotoxic, antimicrobial and anti-inflammatory compounds.
4. Application of various chromatographics techniques and spectrometry to natural products: TLC, GLC and HPLC; Flourimetry and colorimetry. Uses of UV, IR, NMR and mass spectrometry in the structural elucidation of natural products.

5. Problems encountered in and prospects of discovering new drugs from plants. Natural substances as raw materials in drug synthesis. Biomedicinals of recent discovery. Bioevaluation of herbal drugs. Preparation of standardized extracts suitable for incorporation in solid dosage forms like tablets, capsules etc.
6. HERBAL FORMULATIONS : Types of herbal formulations. Recent trends in poly-herbal medicines. Herbal cosmetics and herbal teas. Manufacture, packaging and approach to quality control of herbal formulations. GMP for herbal drug formulations.

M.PH – 204P(c): Pharmacognosy Major – IV Laboratory:

- 1) Representative exercises based on extraction of bioactive compounds listed in theory.
- 2) Preparation of selected poly-herbal formulations.
- 3) Representative exercises based on physical, chemical and biological techniques of evaluation of plant constituents/extracts.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 202(d): Pharmacology Major – II:

CLINICAL RESEARCH :

1. New Drug discovery process and Role of Clinical evaluation of new drugs: Terminologies, Organization, types of clinical research, phases of clinical research, Ethics and Protocol for Clinical Trials.
2. Therapeutic drug monitoring principles

PHARMACOTHERAPEUTICS OF FOLLOWING DISEASES: MANAGEMENT AND CLINICAL PRACTICE GUIDELINES :

3. Hypertension, congestive heart failure, angina pectoris, acute myocardial infarction, cardiac arrhythmia, atherosclerosis, peripheral vascular disorders and coagulation disorders.
4. Drugs used in the treatment of Hyperlipoproteinemias,
5. Pain, ANS, CNS & PNS Disorders. History and principles of anesthesiology.
6. Analgesic-Antipyretic and Anti-Inflammatory agents and Drugs employed in the treatment of Gout.
7. Autocoids: Drug therapy of inflammation. Lipid- Derived Autocoids : Eicosanoids and platelet Activating factor.
8. Gastrointestinal diseases: Peptic ulcer, nausea and vomiting, diarrhea and constipation.
9. Renal diseases: Acute and chronic renal failure, renal dialysis and transplantation, drug doses in renal impairment.
10. Respiratory diseases: asthma, chronic obstructive pulmonary edema. Pulmonary embolism.
11. Hepatic disorders: cirrhosis, hepatitis etc
12. Immunopharmacology: Current concepts in theory and research of drugs for AIDS, vaccines and sera, drug allergy, tissue transplantation, immunostimulants, immunomodulators, immunosuppressant. Knowledge of various *in vitro* and *in vivo* tests carried out in immunological investigation.
13. Infectious diseases: General Guidelines for Rational Use of Antibiotics. Resistance to antibiotics. Diseases & management.
14. Neoplastic disorders: General principles of cancer chemotherapy
15. Endocrine disorders
16. Drug therapy in Geriatrics, Pediatrics, Lactating & Pregnant women.

M.PH – 202P (d): Pharmacology Major – II Laboratory:

1. Bio assays of Ach, Histamine, Oxytocin, Adrenaline, Pancuronium
2. Monitoring of any one marketed drug in biological fluids
3. Determination of pA_2 values of any one antagonist.
4. Evaluation of antiparkinson agents
5. Evaluation of diuretics agents
6. Evaluation of antidepressant agents
7. Evaluation of Antiulcer agents
8. Evaluation of Antibiotic agents
9. Evaluation of Antineoplastic agents
10. Evaluation of Antiinflammatory agents

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH – 203(d): Pharmacology Major – III:

1. MOLECULAR MECHANISM OF DRUG ACTION: Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and phosphatidyl inositol. Ionic channels and their modulators. Application of molecular pharmacology to drug design.
2. ENDOGENOUS BIOACTIVE MOLECULES: such as cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.
3. RECENT TRENDS ON DIFFERENT CLASSES OF RECEPTORS AND DRUGS ACTING ON THEM:
 - a) Angiotensin receptors
 - b) Excitatory amino acid receptors
 - c) Kinin receptors
 - d) Adrenoceptors
 - e) Low molecular weight heparins, hirudins and GP II/IIIa receptor antagonists
 - f) Imidazole receptors
 - g) Cholinergic receptors
 - h) Dopamine receptors
 - i) Serotonin receptors
 - j) Hormone receptors
 - k) GABA and Benzodiazepine receptors
 - l) Opioid receptors
 - m) Purinergic receptors
 - n) Glutamate receptors
4. ION CHANNEL AND THEIR MODULATORS: calcium, potassium, sodium and chloride channels
5. APOPTOSIS: pharmacological and clinical implications
6. Adhesion therapy and cardiac and vascular remodeling
7. Basic Concepts of Chronopharmacology and their implications to Drug Therapy.
8. Basic concepts of high throughput screening

9. Immunopharmacology: antibody dependent and cellular cytotoxicity.
10. Concept of gene therapy and recent development in the treatment of various hereditary diseases. Transgenic mouse and its applications. Human genome mapping and its potential in drug research.
11. Pharmacogenetics: Interracial and individual variability in drug metabolism.

M.PH – 203P (d): Pharmacology Major – III Laboratory:

1. Representative exercises based on topics listed in theory
2. Software based experiments on molecular pharmacology
3. Compilation of literature project on topics included in theory.
4. Other Experiments as may be designed by subject teacher based on contemporary need.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.

M.PH –204 (d): Pharmacology Major – IV:

SCREENING METHODS IN PHARMACOLOGY AND CLINICAL RESEARCH

1. a. Drug discovery process: Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery. Regulations for laboratory animal care and ethical requirements.
- b. Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization. Biological standardization of vaccines and sera, vasopressin, oxytocin, Acetylcholine, Adrenaline, insulin, d-tubocurarine, HCG, hyaluronidase, corticotrophine, pertussis, rabies and plague.
- c. Introduction to biostatistics, parametric and non parametric tests.

2. Preclinical and clinical models employed in the screening of new drugs belonging to following categories

Antifertility agents, sympathomimetics, parasympathomimetics, muscle relaxants (both central and peripheral), sedatives, hypnotics, antiarrhythmic agents, cardiac stimulants, cardiostimulant agents, bronchodilators, antihistaminics, eicosanoids.

Antipsychotic agents, antianxiety agents; nootropic drugs; antidepressant drugs; antiParkinsonian agents; antiepileptics; analgesics and anti-inflammatory agents; antiulcer agents; infarction; antiatherosclerotic drugs; antimalarials; anthelmintics; antidiabetics; models for status epilepticus, intracerebroventricular and other newer techniques of drug administration and development; transgenic animals and other genetically prone animal models.

3. Alternatives to animal screening procedures, cell-line, patch-clamp technique, in-vitro models, molecular biology techniques.

4. Principles of toxicity evaluations, ED₅₀, LD₅₀ and TD values. International guidelines (ICH recommendations).

5. **Pharmacokinetics.**

Drug absorption, drug distribution and transfer of drugs through biological barriers, therapeutic implication in drug action with emphasis on drug transporters., elimination of drug, bioavailability and bioequivalence of drug products and biotransformation of drug.

M.PH –204P (d): Pharmacology Major – IV Laboratory:

Representative exercises based on Screening Methods in pharmacology and clinical Research topics based listed as above.

Sufficient number of Experiments has to be conducted under the above mentioned categories not less than 6 hours per week.