ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2. Every student, selected for admission to PG Pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance in theory, practical, seminar, assignment, journal club, discussion with the supervisor, research work presentation and dissertation shall be maintained by the department/teaching staff of respective courses.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes shall be awarded on the basis of CGPA as follows

First Class with Distinction = CGPA of 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 The Semester grade point average (SGPA):

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the

grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4G4}{C1+C2+C3+C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and AB grade awarded in that semester. For example if a learner has F or AB grade in course 4, the SGPA shall then be computed as:

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4*ZERO}{C1+C2+C3+C4}$$

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/ are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\textbf{CGPA} = \frac{C1S1+C2S2+C3S3+C4S4}{C1+C2+C3+C4}$$

Where C_1,C_2,C_3, C4…is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
Total:	**70 marks**

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
Total:	**30 Marks**

Table 6: Pharmacognosy (MPG)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPG 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPG 102T	Advanced Pharmacognosy - I	4	4	10	20	30	70	100
MPG 103T	Phytochemistry	4	4	10	20	30	70	100
MPG 104T	Industrial Pharmacognostical Technology	4	4	10	20	30	70	100
MPG 105P	Pharmacognosy Practical – I	2	6	15	15	30	70	100
MPG 106P	Pharmacognosy Practical - II	2	6	15	15	30	70	100
MPG 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPG 201T	Medicinal Biotechnology	4	4	10	20	30	70	100
MPG 202T	Advanced Pharmacognosy - II	4	4	10	20	30	70	100
MPG 203T	Indian Systems of Medicine	4	4	10	20	30	70	100
MPG 204T	Herbal Cosmetics	4	4	10	20	30	70	100
MPG 205P	Pharmacognosy Practical - III	2	6	15	15	30	70	100
MPG 206	Comprehensive Viva	2	---	---	---	---	---	50
MPG 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 6: Pharmacognosy (MPG) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPG 302	Journal Club*	2	2	50	---	---	---	50
MPG 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPG 304	Seminar on selected topic	4	4	---	---	---	100	100
MPG 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPG 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPG 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPG 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

PHARMACOGNOSY

PROGRAM OUTCOMES

After completion of the program, the student should be able to

PO1: Design and Perform research projects related to drug discovery from natural resources

PO2: Understand needs of herbal drug industry and productively contribute to solving them

PO3: File documents as per the regulatory requirements for herbal drug products

PO4: Establish herbal drug supply or processing unit

PO5: Prepare herbal drug formulations as per requirements of national or international agencies

PO6: Grow medicinal plants using tissue culture method

PO7: Develop of new herbal drugs via clinical research

PO8: Understand various techniques for herbal analysis

PROGRAM EDUCATIONAL OBJECTIVES

The objectives of the program is to provide comprehensive knowledge to the student to be able to

1. Know the methods used for cultivating herbal drugs and good agricultural practices
2. Know the sources of crude drugs and their chemical nature
3. Know the detailed chemistry of various classes of plant secondary metabolites
4. Understand regulatory aspects governing practice of herbal drug manufacturing
5. Understand the procedure and significance of filing patent
6. Know the significance of nutraceuticals and their market
7. Get thorough knowledge on principles and procedures in crude drug analysis
8. Understand principles of traditional systems of medicine and preparing drug as per their guidelines
9. Be a part of Clinical research team for herbal drugs research

PROGRAM SPECIFIC OUTCOMES

After completion of the course the candidate will gain thorough knowledge on

PSO1: Systematic study of pharmacognosy, including cultivation, collection, storage and utilization of crude drugs

PSO2: Chemical examination of herbal drugs including extraction, isolation and identification of bioactive products from natural resources

PSO3: Systematic clinical and preclinical evaluation of natural products for bioactivity

PSO4: Establishment of herbal drug industry and its maintenance

PSO5: Development of herbal formulations including cosmetics

PSO6: Preparation of drugs as per the principles of traditional medicine

PSO7: Development of tissue culture methods for medicinally important plants

PSO8: Filing of papers for patent protection

MPG102T: Advanced Pharmacognosy I– Theory

Program Objectives: The objectives of the program is to provide comprehensive knowledge to the student to be able

1. to know the methods used for cultivating herbal drugs and good agricultural practices
3. to know the sources of crude drugs and their chemical nature
4. to know the detailed chemistry of various classes of plant secondary metabolites
5. to understand regulatory aspects governing practice of pharmacognosy

Objectives Upon completion of the course, the student shall be able to know the, • Advances in the cultivation and production of drugs • Variousphyto-pharmaceuticals and their source, its utilization andmedicinal value. • Various nutraceuticals/herbs and their health benefits • Drugs of marine origin • Pharmacovigilance of drugs of natural origin

Course outcomes CO2: Marine drug discovery and study of marine natural products CO3: Scope, medicinal value and standardization of nutraceuticals and regulatory aspect of nutraceuticals CO4: Occurrence, isolation, characterization, identification, biosynthesis and activity profile of biologically active natural products. CO5: WHO guideline study for quality and safety monitoring of herbal drugs and study about herb drug, food drug interaction and adverse effect of herbals.

	Lecture Objectives
Unit I	To provide a holistic idea on • the scope of pharmacognosy and introducing the student to different types of herbal materials used in traditional medicine • Significance and methods of maintenance and evaluation of quality of herbal material. • Principles and procedures involved in physicochemical and microscopic methods of studying herbal materials
Unit II	To let the student understand • the Significance of marine environment as potential source of bioactive secondary metabolites. • Methods used for Development and conservation of medicinal plants
UNit III	To introduce the student the concept of functional food and potential of nutaceuticals
Unit IV	To impart comprehensive knowledge on chemistry of various classes of secondary metabolites obtained from various resources

Unit V	Pharmacovigilance and regulatory aspects of pharmacognosy

PHYTOCHEMISTRY (MPG 103T)

Program Objectives:

Upon completion of the course, the student shall be able to know the,

• Different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery

• Phytochemical fingerprinting and structure elucidation of phytoconstituents.

Lecture Objectives

	Lecture Objectives
Unit I	To provide a holistic idea on • used for study of biosynthetic pathways • Biosynthesis of various classes of bioactive secondary metabolites
Unit II	To let the student understand • the methods used for isolation and identification of various classes of secondary metabolites. • Chemistry and biological applications of plant secondary metabolites
UNit III	To let the student obtain comprehensive idea on isolation and analysis selected physochemicals of industrial importance
Unit IV	• Impart the knowledge of ancient systems of medicine and their relevance to modern times • To provide basic principles and mechanisms involved in secondary metabolite production and their biosynthetic pathway study
Unit V	To study in detail the source, chemistry, cultivation method, problems associated with quality and their assessment with specific experimental procedures.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)

Program Objectives

By the end of the course the student shall be able to know,

• The requirements for setting up the herbal/natural drug industry.

• The guidelines for quality of herbal/natural medicines and regulatory issues.

• The patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

	Lecture Objectives
Unit I	To provide a holistic idea on • Financial, infrastructural and technical requirements to start a herbal drug industry • Pilot plant studies
Unit II	To let the student understand • regulatory requirements pertaining to quality of herbal products
UNit III	To let the student obtain comprehensive idea on official Pharmacopoeias/publications of various countries on herbal drugs and formulations
Unit IV	• Impart the knowledge of testing protocols for evaluating herbal formulations
Unit V	Procedures involved in Patent drafting and application especially herbal and other natural products

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

Program OBJECTIVES: Upon completion of the course, the student shall be able to,

• Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.

• Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

	Lecture Objectives
Unit I	To provide a holistic idea on • mechanisms of plant pollination and differentiate between haploid and diploid cells and their role in sexual reproduction
Unit II	To let the student develop • skill in Plant tissue culture techniques for production of genetically modified plants
UNit III	To Develop skill in Hairy root culture for production of different primary and secondary metabolites.
Unit IV	• Impart the knowledge of Different methods of cloning and its applications.
Unit V	Knowledge about • Techniques used for plant genome analysis. • Plant fermentation technology in production of secondary metabolites

ADVANCED PHARMACOGNOSY – II(MPG 202T)

Program OBJECTIVES: Upon completion of the course, the student shall be able to know the, • validation of herbal remedies • methods of detection of adulteration and evaluation techniques for the herbal drugs • methods of screening of herbals for various biological properties

	Lecture Objectives
Unit I	To provide a holistic idea on • the role of ethno botany and ethnopharmacology in drug development
Unit II	To let the student develop skill to • Critically evaluate the use of plant and plant products as medicinal agents
UNit III	To Develop skill in analytical profiling of different classes of phytochemicals
Unit IV	• Discuss the therapeutic actions of main classes of phytochemical and their interactions with other herbs or drugs and become familiar with DNA fingerprinting techniques.
Unit V	Knowledge about • the toxicity and regulations of herbal vs conventional drugs CO6: Students will study the biological screening of herbal drugs and related guidelines.

INDIAN SYSTEMS OF MEDICINE (MPG 203T)

Program OBJECTIVES: After completion of the course, student is able to • To understand the basic principles of various Indian systems of medicine • To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

	Lecture Objectives
Unit I	To provide a holistic idea on • fundamental concepts of Ayurveda, siddha, unani and

	homeopathic system of medicine. Basic principles and healing potentials of Yoga, Naturopathy and Aromatherapy.
Unit II	To let the student develop skill to • perform herbal formulation development and standardization of various traditional formulations. Various purification process (Shodana and Marana concepts)
UNit III	Quality control and quality assurance concepts involved in traditional system of medicine.
Unit IV	• Study the concepts of AYUSH, AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.
Unit V	

HERBAL COSMETICS (MPG 204T)

OBJECTIVES: After completion of the course, student shall be able to,

• Understand the basic principles of various herbal/natural cosmetic preparations

• Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

Program OUTCOME:

	Lecture Objectives
Unit I	• Study of herbal formulations, cosmeceutical and regulatory requirements of herbal drugs along with biological screening for their therapeutic efficacy will help the student to understand the overall process of formulation and development of herbal drugs.
Unit II	• Develop skill in Herbal cosmeceutical development and standardization Raw product analysis
UNit III	• Students will study import and export of herbal cosmetics.
Unit IV	• Students will also become familiar with possible interactions between chemicals and herbs CO5:
Unit V	• Develop skill in Quality control and quality assurance of herbal cosmetics. To learn toxicological and allergen screening techniques

PHARMACOGNOSY (MPG)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analysed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 3:

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED PHARMACOGNOSY - I (MPG 102T)

Unit 1:

Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In- situ conservation of medicinal plants. **12 Hours**

Unit 2:

Marine natural products: General methods of isolation and purification. Study of marine toxins, recent advances in research in marine drugs. Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. **12 Hours**

Unit 3:

Nutraceuticals: Current trends and future scope. Inorganic mineral supplements, vitamin supplements, digestive enzymes, dietary fibres, cereals and grains, health drinks of natural origin, antioxidants, polyunsaturated fatty acids, herbs as functional foods. Formulation and standardization of nutraceuticals, regulatory aspects, FSSAI guidelines. Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following

i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric. **12 Hours**

Unit 4:

Phytopharmaceuticals: Occurrence, isolation and characteristic features (chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids- Ellagic acid
f) Vitamins
g) Tocotrienols and Tocopherols
h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol

i) Miscellaneous **12 Hours**

Unit 5:

Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine. Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. **12 Hours**

REFERENCES

1. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy - Tyler, Brady & Robbers.
3. Modem Methods of Plant Analysis - Peach & M.V. Tracey. Vol 1 & 2
4. Text Book of Pharmacognosy - T.E. Wallis.
5. Marine Natural Products -Vol. 1 to 6.
6. Natural Products: A Lab Guide - Raphael Ikan. Academic Press, 1991.
7. Glimpses of Indian Ethano Pharmacology - P. Pushpangadam. U.L.F. Nyman & V. George. Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal Natural Products (A Biosynthetic Approach) - Paul M Dewick. John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products - Paul J Schewer. 1973.
10. Herbal Drug Industry – R.D. Choudhary. Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants - C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants - C.K. Atal & B.M. Kapoor.
13. Cultivation of Medicinal and Aromatic Crops – A.A. Farooqui & B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants - Peter B Kaufman. 1st ed. CRC Press, New York, 1998.
15. Recent Advances in Phytochemistry - Scikel Runeckles. Vol. 1 & 4. Appleton Century Crofts.
16. Text book of Pharmacognosy - C.K. Kokate, Purohit & Ghokhale. Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology – Ashutoshkar. New Age Publications, New Delhi.

PHYTOCHEMISTRY (MPG 103T)

Unit 1:

Biosynthetic pathways and radio tracing techniques: Constituents & their biosynthesis, isolation, characterization and purification with a special reference to their importance in herbal industries of following phytopharmaceuticals containing drugs:

a) Alkaloids: Ephedrine, quinine, strychynine, piperine, berberine, taxol, vinca alkoloids.
b) Glycosides: Digitoxin, glycyrrhizin, sennosides, bacosides, quercitin.
c) Steroids: Hecogenin, guggulosterone and withanolides
d) Coumarin: Umbelliferone.
e) Terpenoids: Cucurbitacins **12 Hours**

Unit 2:

Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration. Selection and optimization of lead compounds with suitable examples from

the following sources: artemesin, morphine, taxol, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. **12 Hours**

Unit 3:

Extraction and phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and flash column chromatography. **12 Hours**

Unit 4:

Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. **12 Hours**

Unit 5:

Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^{1}H, ^{13}C)

a) Carvone, citral, menthol;
b) Luteolin, kaempferol;
c) Nicotine, caffeine
d) Glycyrrhizin. **12 Hours**

REFERENCES

1. Organic chemistry - I.L. Finar. Vol.II
2. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
3. Pharmacognosy - Tyler, Brady & Robbers
4. Text Book of Pharmacognosy - T.E. Wallis.
5. Clark's isolation and Identification of drugs - A.C. Mottal.
6. Plant Drug Analysis - H. Wagner & S. Bladt. Springer, Berlin.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry - R.F. Deorge.
8. The Chemistry of Natural Products - R.H. Thomson. Springer International ed. 1994.
9. Natural Products Chemistry Practical Manual - Anees A Siddiqui & Seemi Siddiqui.
10. Organic Chemistry of Natural Products - Gurdeep R Chatwal. Vol. 1 & 2.
11. Chemistry of Natural Products – IWPAC, Vol. 1 onwards.
12. Modem Methods of Plant Analysis - Peach & M.V. Tracey, Vol. I & II
13. Medicinal Natural Products (A Biosynthetic Approach) - Paul M Dewick. John Wiley & Sons Ltd., England, 1998.
14. Chemistry of Natural Products - S.V. Bhat, B.A. Nagasampagi & S. Meenakshi. Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants – J. Bruneton. 2nd ed. Intercept Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)

Unit 1:

Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship development, Project selection, project report, technical knowledge, capital venture, plant design, layout and construction. Pilot plant scale up techniques, case studies of herbal extracts. Formulation and production

management of herbals. **12 Hours**

Unit 2:

Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000. **12 Hours**

Unit 3:

Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American Herbal Pharmacopoeia, British Herbal Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. **12 Hours**

Unit 4:

Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols. **12 Hours**

Unit 5:

Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, copyright, patentable subject maters, novelty, non-obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature. Controllers of patents. **12 Hours**

REFERENCES

1. Herbal Drug Industry - R.D. Choudhary. Eastern Publisher, New Delhi, 1996.
2. GMP for Botanicals - Regulatory and Quality Issues on Phytomedicine - Pulok K Mukharjee. 1st ed. Business Horizons Pharmaceutical Publisher, New Delhi, 2003.
3. Quality Control of Herbal Drugs - Pulok K Mukarjee, Business Horizons Pharmaceutical Publisher, New Delhi, 2002.
4. PDR for Herbal Medicines. Medicinal Economic Company, New Jersey, 2000.
5. Indian Herbal Pharmacopoeia - 2002, IDMA, Mumbai.
6. Text Book of Pharmacognosy - C.K. Kokate, Purohit & Gokhlae, Nirali Prakashan, New Delhi, 1996.
7. Text Book of Pharmacognosy and Phytochemistry - Vinod D. Rangar, Part I & II. Career Publication, Nasik, India, 2002.
8. Plant Drug Analysis - H. Wagner & S. Bladt. Springer, Berlin.
9. Standardization of Botanicals: Testing and Extraction Methods of Medicinal Herbs - V. Rajpal, Vol. I. Eastern Publisher, New Delhi, 2004.
10. Phytochemical Dictionary: Handbook of Bioactive Compounds from Plants - J.B. Harborne. 2nd ed. Taylor and Francis Ltd, UK, 1999.
11. Herbal Medicine: Expanded Commission E Monographs - M. Blumenthal. IST Edition, 2004.
12. Drug Formulation Manual - D.P.S. Kohli and D.H. Shah. Eastern Publisher, New Delhi, 1998.

PHARMACOGNOSY PRACTICAL - I (MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography

4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawsonia by TLC/HPTLC method.
6. Methods of extraction

PHARMACOGNOSY Practical – II (MPG 106P)

1. Phytochemical screening
2. Demonstration of HPLC - estimation of glycerrhizin
3. Monograph analysis of clove oil
4. Monograph analysis of castor oil
5. Identification of bioactive constituents from plant extracts
6. Formulation of different dosage forms and their standardisation

Semester 2

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

Unit 1:

1. Introduction to plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signalling, DNA recombinant technology. **12 Hours**

Unit 2:

Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, protoplast fusion, hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. **12 Hours**

Unit 3:

Immobilisation techniques & secondary metabolite production: Immobilization techniques of plant cell and its application on secondary metabolite production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. **12 Hours**

Unit 4

Biotransformation and transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis. **12 Hours**

Unit 5:

Fermentation technology: Application of fermentation technology, production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. **12 Hours**

REFERENCES

1. Plant Tissue Culture - Bhagwani, Vol. 5. Elsevier Publishers.
2. Plant Cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in Biotechnology - P.K. Gupta. Rastogi Publications, New Delhi.
4. An introduction to Plant Tissue Culture - M.K. Razdan. Science Publishers.

5. Experiments in Plant Tissue Culture - John HD & W.R. Lorin. Cambridge University Press.
6. Pharmaceutical Biotechnology - S.P. Vyas and V.K. Dixit. CBS Publishers, New Delhi.
7. Plant Cell and Tissue Culture - Jeffrey W. Pollard & John M Walker, Humana Press.
8. Plant Tissue Culture - Dixon, Oxford Press, Washington DC, 1985
9. Plant Tissue Culture - Street.
10. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
11. Biotechnology - Purohit & Mathur, Agro-Bio, 3rd Revised Edition.
12. Biotechnological Applications to Tissue Culture – Shargool & D. Peter. CKC Press.
13. Pharmacognosy - Varo E Tyler, Lynn R Brady & James E Robberrt. That Tjen, NGO.
14. Plant Biotechnology - Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II (MPG 202T)

Unit 1:

Herbal remedies: Toxicity and regulations. Herbals vs. conventional drugs, efficacy of herbal medicine products, validation of herbal therapies, pharmacodynamic and pharmacokinetic issues. **12 Hours**

Unit 2:

Adulteration and deterioration: Introduction, types of adulteration/ substitution of herbal drugs, causes and measures of adulteration, sampling procedures, determination of foreign matter, DNA finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. **12 Hours**

Unit 3:

Ethnobotany and ethnopharmacology: Ethnobotany in herbal drug evaluation, impact of ethnobotany in traditional medicine, new development in herbals, bio-prospecting tools for drug discovery, role of ethnopharmacology in drug evaluation, reverse pharmacology.

12 Hours

Unit 4:

Analytical profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. **12 Hours**

Unit 5:

Biological screening of herbal drugs: Introduction and need for phyto-pharmacological screening, new strategies for evaluating natural products. In vitro evaluation techniques for antioxidants, antimicrobial and anticancer drugs. In vivo evaluation techniques for anti-inflammatory, antiulcer, anticancer, wound healing, antidiabetic, hepatoprotective, cardio protective, diuretics and antifertility. Toxicity studies as per OECD guidelines. **12 Hours**

REFERENCES

1. Glimpses of Indian Ethano Pharmacology - P. Pushpangadam. U.L.F. Nyman & V. George. Tropical Botanic Garden & Research Institute, 1995.
2. Natural Products: A Lab Guide - Raphael Ikan. Academic Press.
3. Pharmacognosy - G. E. Trease & W.C. Evans. Saunders Edinburgh, New York.
4. Pharmacognosy - Tyler, Brady & Robbers. Lee & Febiger.
5. Modem Methods of Plant Analysis - Peach & M.V. Tracey. Vol I & II. Springer Publishers.
6. Herbal Drug Industry – R.D. Choudhary, Eastern Publishers, New Delhi.

7. Text book of Pharmacognosy - C.K. Kokate, Purohit & Ghokhale. Nirali Prakasshan, 1996.
8. Text Book of Pharmacognosy - T.E. Wallis.
9. Quality Control of Herbal Drugs - Pulok K Mukarjee. Business Horizons Pharmaceutical Publisher, New Delhi, 2002.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text Book of Pharmacognosy and Phytochemistry - Vinod D. Rangar, Part I & II. Career Publication, Nasik, India, 2002.
12. Plant Drug Analysis - H. Wagner & S. Bladt. Springer, Berlin.
13. Standardization of Botanicals: Testing and Extraction Methods of Medicinal Herbs - V. Rajpal. Vol 1. Eastern Publisher, New Delhi, 2004.
14. Herbal Medicine - Expanded Commission E Monographs - M. Blumenthal.

INDIAN SYSTEMS OF MEDICINE (MPG 203T)

Unit 1:

Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine. Different dosage forms of the Indian system of medicine (ISM).

Ayurveda: Ayurvedic Pharmacopoeia. Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, purification process (Suddhi).

12 Hours

Unit 2:

Naturopathy, Yoga and Aromatherapy practices

a) Naturopathy - Introduction, basic principles and treatment modalities.
b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils. **12 Hours**

Unit 3:

Formulation development of various systems of medicine. Salient features of the techniques of preparation of some of the important class of formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, shelf life and stability studies of ISM formulations. **12 Hours**

Unit 4:

Schedule T – Good Manufacturing Practice of ISM. Components of GMP (Schedule – T) and its objectives, infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias. **12 Hours**

Unit 5:

TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU **12 Hours**

REFERENCES

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines - H. Panda. National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine - Kaviraj Nagendranath Sengupata. Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia - Formulary of Ayurvedic Medicines. IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia - Formulary of Homeopathic Medicines. IMCOPS, Chennai.
6. Homeopathic Pharmacy: An Introduction & Hand Book - Steven B Kayne. Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia. IDMA, Mumbai.
8. British Herbal Pharmacopoeia. British Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality Issues on Phytomedicine - Pulok K Mukharjee. Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India. Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition – Swaminathan. Bappco, Bangalore.
12. Clinical Dietetics and Nutrition - F.P. Antia. Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living - V.K. Yoga & Vivekananda Yoga. Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG 204T)

Unit 1:

Introduction: Herbal/natural cosmetics. Classification & Economic aspects.

Regulatory Provisions in relation to manufacture of cosmetics: License, GMP, offences & Penalties, Import & Export of herbal/natural cosmetics. Industries involved in the production of herbal/natural cosmetics. **12 Hours**

Unit 2:

Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors and some functional herbs. Preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. **12 Hours**

Unit 3:

Herbal Cosmetics: Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, cleansing cream, lotions, face powders, face packs, lipsticks, bath products, soaps and baby product. Preparation and standardisation of tonic, bleaches, dentifrices (mouth washes & tooth pastes), cosmetics for nails. **12 Hours**

Unit 4:

Cosmeceuticals of herbal and natural origin: Hair growth formulations, shampoos, conditioners, colorants & hair oils, fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. **12 Hours**

Unit 5:

Analysis of cosmetics, toxicity screening and test methods: Quality control and toxicity studies as per Drugs and Cosmetics Act. **12 Hours**

REFERENCES

1. Herbal Cosmetics (Hand book) - H. Panda. Asia Pacific Business Press Inc., New Delhi.
2. Modern Cosmetics - E.G. Thomson. Universal Publishing Corporation, Mumbai.
3. Cosmetics: Formulation, Manufacturing & Quality Control - P.P. Sharma. Vandana Publications, New Delhi.
4. Handbook of Aromatic Plants – K.B. Supriya. Pointer Publishers, Jaipur.
5. Aromatic Plants (Horticulture Science Series) – P. Skaria. New India Publishing Agency, New Delhi.
6. Aromatheraphy (A Complete Guide to the Healing Art) - Kathi Keville & Mindy Green. Sri Satguru Publications, New Delhi.
7. Herbal Cosmetics & Ayurvedic Medicines (EOU) – P.K. Chattopadhyay. National Institute of Industrial Research, Delhi.
8. Cosmetics Science and Technology - Balsam MS & Edward Sagarin. Wiley Interscience, New York.

PHARMACOGNOSY PRACTICAL – III (MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

General research methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality. **12 Hours**

Unit 4:

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net