Ordinance Governing

Master of Pharmacy

M. Pharm. Degree Course

***

Syllabus / Curriculum

2017 - 18

KLE UNIVERSITY
EMPOWERING PROFESSIONALS

Accredited **'A' Grade** by NAAC
Placed in Category 'A' by MHRD(GoI)

KLE UNIVERSITY

JNMC Campus, Nehru Nagar, Belgaum - 590 010. Karnataka, INDIA.
Phone : +91 0831-2472777, 2493779 FAX : +91 0831-2493777
E-mail : info@kleuniversity.edu.in Website : www.kleuniversity.edu.in

Edition Year : 2017

E-mail: registrar@kleuniversity.edu.in

Director, Academic Affairs

Email: diracademic@kleuniversity.edu.in

KLE University

JNMC Campus, Nehru Nagar,

Belgaum-590010

Ph: 0831-2472777

e-mail:info@kleuniversity.edu.in

Price Rs: 170/-only

Printed at:

OMEGA OFFSET

4574, Shetty Galli, Belgaum.

☎ : 2424124, 2433429

Fax : 4204124

VISION

To be an outstanding University of excellence ever in pursuit of newer horizons to build self reliant global citizens through assured quality educational programs.

MISSION

- To promote sustainable development of higher education consistent with statutory and regulatory requirements.
- To plan continuously provide necessary infrastructure, learning resources required for quality education and innovations.
- To stimulate to extend the frontiers of knowledge, through faculty development and continuing education programs.
- To make research a significant activity involving staff, students and society.
- To promote industry / organization, interaction/collaborations with regional/national / international bodies.
- To establish healthy systems for communication among all stakeholders for vision oriented growth.
- To fulfill the national obligation through rural health missions.

OBJECTIVES

The objectives are to realize the following at university and its constituent institutions:

- To implement effectively the programs through creativity and innovation in teaching, learning and evaluation.
- To make existing programs more careers oriented through effective system of review and redesign of curriculum.
- To impart spirit of enquiry and scientific temperament among students through research oriented activities.
- To enhance reading and learning capabilities among faculty and students and inculcate sense of life long learning.
- To promulgate process for effective, continuous, objective oriented student performance evaluation.
- To ordinate periodic performance evaluation of the faculty.
- To incorporate themes to build values. Civic responsibilities & sense of national integrity.
- To ensure that the academic, career and personal counseling are in-built into the system of curriculum delivery.
- To strengthen, develop and implement staff and student welfare programs.
- To adopt and implement principles of participation, transparency and accountability in governance of academic and administrative activities.
- To constantly display sensitivity and respond to changing educational, social, and community demands.
- To promote public-private partnership.

INSIGNIA

The Emblem of the University is a Philosophical statement in Symbolic.

The Emblem...

A close look at the emblem unveils a pillar, a symbol of the "University of Excellence" built on strong values & principles.

The Palm and the Seven Stars...

The Palm is the palm of the teacher- the hand that acts, promises & guides the students to reach for the Seven Stars...

The Seven Stars signify the 'Saptarishi Dnyanamandal", the Great Bear-a constellation made of Seven Stars in the sky, each signifying a particular Domain. Our culture says: The true objective of human birth is to master these Knowledge Domains.

The Seven Stars also represent the Saptarishis, the founders of KLE Society whose selfless service and intense desire for "Dnyana Dasoha" laid the foundation for creating the knowledge called KLE Society.

Hence another significance of the raised palm is our tribute to these great Souls for making this University a possibility.

Empowering Professionals...

'Empowering Professionals', inscription at the base of the Emblem conveys that out Organization with its strength, maturity and wisdom forever strive to empower the student community to become globally competent professionals. It has been a guiding force for many student generations in the past, and will continue to inspire many forth coming generations.

KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research)

[Established under Section 3 of the UGC Act, 1956 vide Government of India Notification No. F. 9-19/2000-U.3(A)]

Accredited 'A' Grade by NAAC

Office of the Registrar, KLE University,

JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India

Ph: 0831-2472777/2493779 Fax : 0831-2493777 Web: http:/ / www.kleuniversity.edu.in E-mail: info@kleuniversity.edu.in

Ref. No. KLEU/AC/10-11/ 3rd April 2010

NOTIFICATION

Sub : **Ordinance governing the syllabus/curriculum for Master of Pharmacy Course**

Ref : Minutes of the meeting of the Academic Council of the University held on 13th March 2010.

In exercise of the powers conferred under Rule A-04 (i) of the Memorandum of Association of the University, the Academic Council of the University is pleased to approve the Ordinance governing the syllabus / curriculum for the following **Master of Pharmacy Course** in its meeting held on 13th March 2010.

The Ordinance shall be effective for the students admitted to **Master of Pharmacy Course** under the Faculty of Pharmacy in the constituent college of the University viz. KLEs College of Pharmacy, Belgaum from the academic session 2009-10 onwards.

By Order

REGISTRAR

To

The Dean,
Faculty of Pharmacy
KLEs College of Pharmacy
BELGAUM.

CC to :

1. The Secretary, University Grants Commission, New Delhi.
2. The PA to Hon. Chancellor, KLE University, Belgaum.
3. The Special Officer to Hon. Vice-Chancellor, KLE University, Belgaum.
4. All Officers of the University - Academic Affairs / Examination Branch.

CONTENTS

CHAPTER – I:

REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm. Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate 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.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

1. The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours.Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These

credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both 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.

9. Course of study

The specializations in M.Pharm program is given in Table 1.

S.No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Pharmaceutical Chemistry	MPC
3.	Pharmaceutical Quality Assurance	MQA
4.	Pharmacy Practice	MPP
5.	Pharmacology	MPL
6.	Pharmacognosy	MPG

The course of study for M.Pharm. specializations shall include Semester wise Theory & Practical as given in Table – 2 to 7. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 7.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 3: Course of study for M. Pharm.

(Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC102T	Advanced Organic Chemistry-I	4	4	4	100
MPC103T	Advanced Medicinal Chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 4: Course of study for M. Pharm.

(Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 5: Course of study for M. Pharm.

(Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
	Semester I				
MPP101T	Clinical Pharmacy Practice	**4**	**4**	**4**	**100**
MPP102T	Pharmacotherapeutics-I	4	4	4	100
MPP103T	Hospital & Community Pharmacy	4	4	4	100
MPP104T	Clinical Research	4	4	4	100
MPP105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
	Semester II				
MPP201T	Principles of Quality Use of Medicines	4	4	4	100
MPP202T	Pharmacotherapeutics II	4	4	4	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 6: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
	Semester I				
MPL101T	Modern Pharmaceutical Analytical Techniques	**4**	**4**	**4**	**100**
MPL102T	Advanced Pharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
	Semester II				
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 7: Course of study for M. Pharm.

(Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./Wk	Marks
	Semester I				
MPG101T	Modern Pharmaceutical Analytical Techniques	**4**	**4**	**4**	**100**
MPG102T	Advanced Pharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
	Semester II				
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG202T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table – 8: Course of study for M. Pharm. III Semester

(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	**35**	**21**

* Non University Exam

Table – 9: Course of study for M. Pharm. IV Semester

(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
	Total	35	20

Table – 10: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities(Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum = 02 Maximum = 07*
Total Credit Points	Minimum = 95 Maximum = 100*

*Credit Points for Co-curricular Activities

Table – 11: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held Outside India

International Journal: The Editorial Board outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the

University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm. specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.

ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.

iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.

v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 12.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Table – 12: Schemes for internal assessments and end semester examinations (Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total MarKs
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPH102T	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH103T	Modren Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
MPH104T	Regulatory Affair	10	15	1Hr	25	75	3Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1Hr	25	75	3Hrs	100
MPH205P	Pharmaceutics Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table – 13: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester I								
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPC1012T	Advanced Organic Chemistry-I	10	15	1Hr	25	75	3Hrs	100
MPC103T	Advanced Medicinal Chemistry	10	15	1Hr	25	75	3Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1Hr	25	75	3Hrs	100
MPC105P	Pharmaceutical Chemistry Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPC201T	Advanced Spectral Analysis	10	15	1Hr	25	75	3Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1Hr	25	75	3Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1Hr	25	75	3Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1Hr	25	75	3Hrs	100
MPC205P	Pharmaceutical Chemistry Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table – 14: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MQA102T	Quality Management System	10	15	1Hr	25	75	3Hrs	100
MQA103T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hrs	100
MQA104T	Product Development and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
MQA105P	Pharmaceutical Quality Assurance Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
MQA201T	Hazards and Safety Management	10	15	1Hr	25	75	3Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6Hrs	50	100	6Hrs	10
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table – 15: Schemes for internal assessments and end semester examinations ((Pharmacy Practice)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester I								
MPP101T	Clinical Pharmacy Practice	10	15	1Hr	25	75	3Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1Hr	25	75	3Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1Hr	25	75	3Hrs	100
MPP104T	Clinical Research	10	15	1Hr	25	75	3Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPP201T	Principles of Quality Use of Medicines	10	15	1Hr	25	75	3Hrs	100
MPP202T	Pharmacotherapeutics II	10	15	1Hr	25	75	3Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1Hr	25	75	3Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1Hr	25	75	3Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table – 16: Schemes for internal assessments and end semester examinations (Pharmacology)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPL102T	Advanced Pharmacology-I	10	15	1Hr	25	75	3Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1Hr	25	75	3Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1Hr	25	75	3Hrs	100
MPL105P	Pharmacology Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPL201T	Advanced Pharmacology II	10	15	1Hr	25	75	3Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1Hr	25	75	3Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1Hr	25	75	3Hrs	100
MPL204T	Clinical Research and Pharmacovigilance	10	15	1Hr	25	75	3Hrs	100
MPL205P	Pharmacology Practical- II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table – 17: Schemes for internal assessments and end semester examinations (Pharmacognosy)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester I								
MPG101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPG102T	Advanced Pharmacognosy-1	10	15	1Hr	25	75	3Hrs	100
MPG103T	Phytochemistry	10	15	1Hr	25	75	3Hrs	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1Hr	25	75	3Hrs	100
MPG105P	Pharmacognosy Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
MPG201T	Medicinal Plant biotechnology	10	15	1Hr	25	75	3Hrs	100
MPG202T	Advanced Pharmacognosy-II	10	15	1Hr	25	75	3Hrs	100
MPG203T	Indian system of medicine	10	15	1Hr	25	75	3Hrs	100
MPG204T	Herbal cosmetics	10	15	1Hr	25	75	3Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table – 18: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
Semester III								
MRM301T	Research Methodology and Biostatistics*	10	15	1Hr	25	75	3Hrs	100
	Journal club	-	-	-	25	-	-	25
	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
	Research work*	-	-	-	-	350	1Hr	350
Total							**525**	
Semester IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1Hr	400
Total							**500**	

***Non University Examination**

11.2. Internal assessment: Continuous mode

The marks allocated for for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 19: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 20: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	**8**	**10**
90 – 94	**6**	**7.5**
85 – 89	**4**	**5**
80 – 84	**2**	**2.5**
Less than 80	**0**	**0**

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular courseincluding internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once

in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 21: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and IIsemesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, 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 in Table – 22.

Table – 22: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. 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 obtainedin all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C_1, C_2, C_3 and C_4 and the student's grade points in these courses are G_1, G_2, G_3 and G_4, respectively, and then students' SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

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 ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO}}{C_1 + C_2 + C_3 + C_4}$$

19. 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 statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/ are passedby 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:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,.... is the total number of credits for semester I,II,III,.... and S_1,S_2, S_3,....is the SGPA of semester I,II,III,....

20. Declaration of class

The class 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

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation / Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

- After completion of course student is able to know about, Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60Hrs

1. **a. UV-Visible spectroscopy:** Introduction, Theory, Laws, 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 (Characterestics 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. **10 Hrs**

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 Hrs**

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. **10 Hrs**

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 **10 Hrs**

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. **10 Hrs**

6. **a. Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.

   b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. **10 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, 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, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOGNOSY - I

(MPG 102T)

SCOPE

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

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

- Advances in the cultivation and production of drugs
- Various phyto-pharmaceuticals and their source, its utilization and medicinal value
- Various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

THEORY **60 Hrs**

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 Insitu conservation of medicinal plants. **12 Hrs**

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 Hrs**

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 neutraceuticals, 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 Hrs**

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

   a) Carotenoids – i) á and â - Carotene ii) Xanthophyll (Lutein)

   b) Limonoids – i) d-Limonene ii) á – 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 Hrs**

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 Hrs**

REFERENCES (Latest Editions of)

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh,
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam.Ulf 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 by RD. Choudhary, Eastern Publisher, New Delhi, 1996.

11. Cultivation of Medicinal Plants by 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, AA Farooqui and B.S. Sreeramu. University Press, 2001.

14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998

15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- 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)

SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto-constituents

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.

THEORY **60 Hrs**

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 phyto-pharmaceuticals 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 Hrs**

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 source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. **12 Hrs**

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 Hrs**

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

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

   a. Carvone, Citral, Menthol

   b. Luteolin, Kaempferol

   c. Nicotine, Caffeine iv) Glycyrrhizin. **12 Hrs**

REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol.II.
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui.
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II.
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

(MPG 104T)

SCOPE

To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

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.

THEORY **60 Hrs**

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 Hrs**

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 Hrs**

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 Hrs**

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

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 Hrs**

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

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.
7. Phytochemical screening.
8. Demonstration of HPLC- estimation of glycerrhizin.
9. Monograph analysis of clove oil.
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts.
12. Formulation of different dosage forms and their standardisation.

MEDICINAL PLANT BIOTECHNOLOGY

(MPG 201T)

SCOPE

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

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

THEORY 60 Hrs

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 signaling, DNA recombinant technology. **12 Hrs**

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. **15 Hrs**

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. **15 Hrs**

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. **13 Hrs**

5. **Fermentation technology:** Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. **05 Hrs**

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II

(MPG 202T)

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/ natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

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

THEORY 60 Hrs

1. **Herbal remedies –** Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues. **12 Hrs**
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 Hrs**
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 Hrs**
4. **Analytical Profiles of herbal drugs:** Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. **12 Hrs**
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 Hrs

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf .Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

INDIAN SYSTEMS OF MEDICINE

(MPG 203T)

SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

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.

THEORY **60 Hrs**

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine Different dosage forms of the 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 Hrs**

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 Hrs**

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 Hrs**

4. Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives, Infrastructural

requirements, working space, storage area, machinery and equipments, 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 Hrs**

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

REFERENCES (Latest Editions of)

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 Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS

(MPG 204T)

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

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

THEORY **60 Hrs**

1. **Introduction:** Herbal/natural cosmetics, Classification & Economic aspects. Regulatory Provisions 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 Hrs**

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 Hrs**

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 the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails. **12 Hrs**

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 Hrs**

5. Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act. **12 Hrs**

REFERENCES (Latest Editions of)

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

HERBAL COSMETICS PRACTICALS
(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.

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

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.

UNIT – II

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.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, 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.

UNIT – IV

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.

UNIT – V

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