आईएफटीएम विश्वविद्यालय, मुरादाबाद, उत्तर प्रदेश

IFTM University, Moradabad, Uttar Pradesh

NAAC ACCREDITED

School of Pharmaceutical Sciences
IFTM UNIVERSITY, MORADABAD.
www.iftmuniversity.ac.in

Study & Evaluation Scheme of
Master of Pharmacy

Programme	:	***Master in Pharmacy (Pharmacognosy)***
Course Level	:	***Post Graduate Degree***
Duration	:	***Four Semester (two academic year) Full Time***
Medium of instruction	:	***English***
Minimum Required Attendance	:	***80%***
Total Credit Points	:	***Minimum=95, Maximum=100***

Programme Outcomes (POs):
On completion of the M. Pharm. program, a student will be able to:

- Explain the knowledge of the basics and advanced pharmaceutical sciences and the ability to acquire, manage and use current information with problem solving approach.
- Perform the synthesis, development of analytical techniques for identification, characterization and quantification of drugs, formulation, pharmacological, pharmacognostical, biotechnological and regulatory aspects of drugs and biomolecules.
- Undergo the applied and interdisciplinary research for betterment of society.
- Comply and work on rules and regulations involved in the drug discovery & development, manufacture and other allied area of the field.
- Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
- Apply critical thinking skills, including investigation, application, analysis, creativity, evaluation of information, data and documents related to research.
- Tackle professional challenges through lifelong learning attitude.
- Demonstrate the ability to plan and implement professional activities.
- Act efficiently as a leader in the diverse areas of the profession including writing research papers and articles of contemporary trends.
- Apply the knowledge and skills to gain recognition in professional circle as well as society.
- Make initiatives to create awareness in society about the effective and safe use of medicines.
- Exercise ethical practices and moral values in personal and professional endeavors.

2016

THE MASTER OF PHARMACY (M. PHARM.)

COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS

PHARMACY COUNCIL OF INDIA
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

Table of Contents

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely–

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 4years ofB.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

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 semestershall 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.

Credit assignment

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 isdependent 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 laboratoryhours perweek throughoutsemestercarries acredit 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 beconsidered as theory course and multiplied by 1.

Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However basedon the credit points earned bythe 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. Coursesgenerally progress in sequence, building competencies andtheir positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given inthe 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.

Table – 1: M.Pharm. Specialization with Code

S. No.	Specialization	Code
1.	Pharmacognosy	MPG

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

Table – 2: 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-I	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
MPG111P	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
MPG222P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 3: Course of study for M. Pharm (Pharmacognosy). III Semester

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
MPG302	Journal club	1	1
MPG303	Discussion / Presentation (Proposal Presentation)	2	2
MPG304	Research Work	28	14
Total		35	21

* Non University Exam

Table – 4: Course of study for M. Pharm (Pharmacognosy). IV Semester

Course Code	Course	Credit Hours	Credit Points
MPG 401	Journal Club	1	1
MPG 402	Discussion / Presentation (Proposal Presentation)	3	3
MPG403	Research Work and Colloquium	31	16
Total		35	20

Table – 5: 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

MPG- Pharmacognosy

Table – 6: 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 sessional exam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 7.

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respectiveuniversity except for the subject with asterix symbol (*) in table I and IIfor which examinations shall be conducted by the subject experts atcollege level and the marks/grades shall be submitted to the university.

Table – 7: Schemes for internal assessments and end semester

(Pharmacognosy- MPG)

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	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG105P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPG111P	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPG201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG202T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG20 3T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MPG222P	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 8: 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 Biotastics*	10	15	1 Hr	25	75	3 Hrs	100
MPG302	Journal club	-	-	-	25	-	-	25
MPG303	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
MPG304	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
MPG401	Journal club	-	-	-	25	-	-	25
MPG402	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
MPG403	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

MPG–
Pharmacognosy

Internal assessment: Continuous mode

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

Table – 9: 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 – 10: 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

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 11. The exact dates of examinations shall be notified from time to time.

Table – 11: 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 beadmitted 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

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 – 12.

Table – 12: 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 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:

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

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), tillthe course(s) is/are passed. Whenthe course(s) is/are passedby obtaining a passgrade on subsequent examination(s) theCGPA

shall only reflect the new grade and notthe failgrades earned earlier.The CGPA is calculated as:

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

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	50Marks
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 andanswer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates whofail 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 I 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 hasto 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,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY — 60 Hrs

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. — 12 Hrs

   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

   Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

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.1 — 12 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	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 X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types ofcrystals and applications of X-raydiffraction.	10 Hrs
6	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 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	10 Hrs

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.

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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.

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 theirhealth 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 In- situ 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 andtheir 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, nameof marker compounds and their chemical nature, medicinal uses andhealth 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) 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 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

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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: 12 Hrs
   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

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 12 Hrs

assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

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) 12 Hrs

a. Carvone, Citral, Menthol
b. Luteolin, Kaempferol
c. Nicotine, Caffeine iv) Glycyrrhizin.

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, plantdesign, 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. 12 Hrs

Quality assurance in herbal/natural drug products.
Concepts of TQM, GMP, GLP, ISO-9000.

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.

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 byM.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 — 13 Hrs

plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

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 andevaluation 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 printingtechniques 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 12 Hrs

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.

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. Plantdrug 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 SYSTEM 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 — 12 Hrs
   Different dosage forms of the ISM.
   Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and biocrudedrugs withreferences to: Identity, purityand quality.
   Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

2 Naturopathy, Yoga and Aromatherapy practices — 12 Hrs
   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.

3 Formulation development of various systems of medicine — 12 Hrs
   Salient features of the techniques of preparation of someof the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization,
   Shelf life and Stability studies of ISM formulations.

4	Schedule T – GoodManufacturing 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 & Handbook, 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.

PHARMACOGNOSY PRACTICAL-II
(MPG205P)

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 lipbalm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets andcapsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.

Semester III

MRM301T - 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 care.

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