

MINUTES OF MEETING

Agenda: The Meeting was convened to approve the Ordinance and Syllabus of Doctor of Pharmacy (Pharm.D & Pharm.D [Post Baccalaureate (PB)], M.Pharm (Pharmaceutics, Pharmacognosy, Pharmaceutical Chemistry, Pharmacology and Regulatory affairs) and Diploma in Pharmacy (D.Pharm) through the Member of Board of Studies (BOS) on dated 14/07/2019 (Sunday) from 12:30 PM at office of Head of the Department Pharmacy, Dr. Bhimrao Ambedkar University Agra, Khandari Campus for Institute of Pharmacy and Paramedical Sciences for the session 2020-21 onwards.

The Following Members concerned with Subject were invited as Mentioned below

- Head of the Department
 (Department of Pharmacy)
- Prof. A Pandurangan
 (Maharishi Markandeshwar (Deemed to be University, Mullana Ambala (Haryana)
- Prof. Pawan Gautam
 (Department of Pharmacy, S.N Medical College, Agra)
- Prof. Sudhir Kumar
 (BBS Institute of Pharmaceuticals and Allied Health Sciences, Greater Noida)
- Dr. Ravi Shekhar Sharma (Department of Pharmacy)
- Mr. Manoj Kr. Yadav(Department of Pharmacy)
- Dr. Jaybir Singh
 (Department of Pharmacy)
- 8. Dr. Arshad Ahmad
 (Department of Pharmacy)
- Mrs. Pratibha Mishra
 (Department of Phamracy)
- Mrs. Pooja Sharma
 (Department of Pharmacy)

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Resolution: Prof. Brijesh Kumar Tiwari, Head, Department of Pharmacy has Chaired meeting of Board of Studies, aforementioned Members were present in the meeting. Meeting was started with agenda to approve the ordinance and syllabus of Doctor of Pharmacy (Pharm.D & Pharm.D [Post Baccalaureate (PB)], M.Pharm (Pharmaceutics, Pharmacognosy, Pharmaceutical Chemistry, Pharmacology and Regulatory affairs) and Diploma in Pharmacy (D.Pharm) was adopted as per the regulations of Pharmacy Council of India. Also discussed that any amendments as per Pharmacy Council of India will be incorporated accordingly.

The appointment of faculty should be done on the basis of qualification and experience prescribed under the "Minimum Qualification for Teachers in Pharmacy Institutions Regulation 2014", as per the Gazette of India (notification no 325, Extraordinary), published on November 12 2014 by the Pharmacy Council of India The Number of Seats will be according to Regulatory body (Pharmacy Council of India). The resolution was passed with vote of thanks and approved.

The Following Members were Present

Prof. Brijesh Kumar Tiwari (Head, Department of Pharmacy)

External Expert (Prof. A Pandurangan)

External Expert (Prof. Pawan Gautam)

External Expert (Prof. Sudhir Kumar)

(Mr. Manoj Kr. Yadav) (Dr. Jaybir Singh) (Dr. Arshad Ahmad) (Mrs. Pratibha Mishra) (Mrs. Pooja Sharma)

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डा० भीमराव आंबेडकर विश्वविद्यालय,आगरा

(पूर्ववर्तीः आगरा विश्वविद्यालय, आगरा)

विद्या परिषद् की बैठक दिनांक 31.07.2019 का कार्यवृत्त

विद्या परिषद् की बैठक दिनांक 31.07.2019 को पूर्वान्ह् 11:00 बजे जे0पी0 सभागार, खन्दारी परिसर आगरा में सम्पन्न हुई, जिसमें निम्नलिखित सदस्य उपस्थित हुये :-

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8. डा० हेमा पाठक

10. प्रो0 मनोज कुमार श्रीवास्तव

. 12. डा० प्रताप सिंह

14 डा० के०पी० सिंह

16. डा० आर०के०एस० धाकरे

18. डं0 मंजूलता शर्मा

20. प्रो0 हरबंस सिंह सोंलकी

22. प्रो0 मीनाक्षी श्रीवास्तव

24. डा० यदुवीर सिंह चौहान

26. प्रो0 मनुप्रताप सिंह

28. डा० जी०के० गुप्ता

30. डा० एन०के० सिंह

32. डा० झिलमिल गुप्ता

34. प्रो० यू०सी० शर्मा

3. डा० जयप्रकाश सिंह

5. प्रो0 बी०पी० सिंह

7. डा० एस०के० कठेरिया

9. डा० नीता गुप्ता

11. डा० सुमन कुमार

13. प्रो0 दीपमाला श्रीवास्तव

15. डा० यशपाल सिंह

17. डा० अलका अग्रवाल

19. डा० विपिन कुमार

21. डा० पीयूष त्यागी

23. प्रो0 विनीता सिंह

25. प्रो० वी०के० सारस्वत

27. डा० आर०के० सिंह

29. प्रो० यू०एन० शुक्ला

31. डा० अनिता गुप्ता

33. प्रो० मोहम्मद अरशद

35. प्रो० अजय तनेजा

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 विद्या परिषद् की पूर्व बैठक दिनांक 27.09.2018, आकिस्मक बैठक दिनांक 21.12.2018 एवं दिनांक 19.06.2019 के कार्यवृत्त की सम्पुष्टि करना।

(परिशिष्ट-1)

निर्णय:-विद्या परिषद् द्वारा दिनांक 27.09.2018, आकस्मिक बैठक दिनांक 21.12.2018 एवं दिनांक 19.06.2019 के कार्यवृत्तों को सम्पुष्टि प्रदान की गई।

प्राचार्य, आर0बी0एस0 कालेज के पत्र दिनांक 25.09.2018 के द्वारा विश्वविद्यालय अनुदान आयोग, नई दिल्ली के द्वारा नेशनल स्किल क्वालीफिकेशन फ्रेमवर्क (एनएसक्यूएफ) स्कीम के अर्न्तगत महाविद्यालय द्वारा निम्न पाठ्यक्रमों को संचालित करने के अनुमोदन पर विचार करना:-

Programme	e/Courses
B.Voc. 1. Multimedia Animation and Graphic Design 2. Nutrition and Health Case Sci. 3. Analytical Instrumentation	Community College 1. Plant Nursery & Propagation Tech. 2. Green House Tech. 3. Holistic and Sustainable Agriculture 4. Dairy Products

निर्णय:-विद्या परिषद् द्वारा उपरोक्त पाठ्यकमों को अनुमोदन प्रदान किया गया।

विद्या परिषद् द्वारा फार्मेसी एण्ड पैरामैडिकल साइंसेज, खन्दारी आगरा की एकडेमिक कमेटी की बैठक
 दिनांक 14.07.2019 की संस्तुतियों के अनुमोदन पर विचार।

(परिशिष्ट-3)

निर्णयः-विद्या परिषद् द्वारा फार्मेसी एण्ड पैरामैडिकल साइंसेज, खन्दारी आगरा की एकेडेमिक कमेटी की बैठक दिनांक 14.07.2019 की केवल अध्यादेश को अनुमोदन प्रदान कया गया। प्रशासनिक संस्तुतियों पर अलग से कार्यवाही किये जाने की संस्तुति की गयी।

4. विद्या परिषद् द्वारा भौतिक विज्ञान विभाग, खन्दारी, आगरा की एकेडेमिक कमेटी की बैटक दिनांक 30.07.2016, 10.11.2017 एवं 12.10.22018 की संस्तुतियों के अनुमोदन पर विचार।

(परिशिष्ट -4)

निर्णय:-विद्या परिषद् द्वारा भौतिक विज्ञान विभाग, खन्दारी, आगरा की एकेडेमिक कमेटी की बैठक दिनांक 30.07.2016, 10.11.2017 एवं 12.10:22018 की संस्तुतियों को अनुमोदन प्रदान किया गया।

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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

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/extracurricular 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 9. 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.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Pharmaceutical Chemistry	MPC
3.	Pharmaceutical Regulatory Affairs	MRA
4.	Pharmacology	MPL
5.	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 less than that shown in Table -2.

Table - 2: Course of study for M. Pharm. (Pharmacognosy)

	ne – 2: Course of study for		•	cognosy,	
Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
	Semes	ter 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
	Semest	ter II			
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	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 - 3: 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 - 4: 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 - 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

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 sessionalexam and before the end semester exam.

11. Examinations/Assessments

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

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.

Tables - 7: Schemes for internal assessments and end semester examinations (Pharmacognosy-MPG)

		Internal Assessment			t	End Semester Exams		Tota
Course Code	Course	Contin uous Mode		sional cams Durati on	Tot al	Mar ks	Durati on	l Mar ks
		:	SEMEST	ER I				
MPG10 1T	Modern Pharmaceutica I Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognos y-1	10	15	1 Hr	25	75	3 Hrs	100
MPG10 3T	Phytochemistr y	10	15	1 Hr	25	75	3 Hrs	100
MPG10 4T	Industrial Pharmacognos tical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG10 5P	Pharmacognos y Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
		٦	Γotal					650
		S	SEMEST	ER II				
MPG20 1T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognos y-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
MPG20 4T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG20 5P	Pharmacognos y Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total							650	

Tables – 08: Schemes for internal assessments and end semester examinations (Semester III&IV)

		Internal Assessment				End Semester Exams		
Course Code	Course	Conti		sional xams	Tot	Mark	Durati	Tota 1 Mark s
		s Mode	Mark s	Durati on	al	S	on	~
			SEMEST	ΓER III				
MRM30 1T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	J ournal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
			Total					525
			SEMEST	TER IV				
-	J ournal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total							500	

^{*}Non University Examination

11.2. Internal assessment: Continuous mode

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

Table - 09: 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

	Table 101 Cardenies 101 the another of marks 101 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 8, 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 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 – 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	0	10	Outstanding
80.00 – 89.99	Α	9	Excellent
70.00 – 79.99	В	8	Good
60.00 – 69.99	С	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 obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

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

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, the SGPA shall then be computed as:

SGPA =
$$C_1G_1 + C_2G_2 + C_3G_3 + C_4* ZERO$$

 $C_1 + C_2 + C_3 + C_4$

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:

$$CGPA = \begin{array}{c} C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 \\ \\ C_1 + C_2 + C_3 + C_4 \end{array}$$

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 Communication skills		100 Marks 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 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 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.

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

THEORY 60 Hrs

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

12

Hrs

- 3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass 10 Spectroscopy, Different types of ionization like electron impact, Hrs 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.
- 4 Chromatography: Principle, apparatus, instrumentation, 10 chromatographic parameters, factors affecting resolution, isolation Hrs of drug from excipients, data interpretation and applications of the following:
 - a) Thin Layer chromatography
 - b) High Performance Thin Laver 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
- 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 of crystals and applications of X-ray diffraction.

6 Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.
10
Hrs

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.

REFERENCES

- L. Spectrometric Identification of Organic compounds Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
- 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.
- Quantitative Analysis of Drugs in Pharmaceutical formulation P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
- Pharmaceutical Analysis Modern Methods Part B J W Munson, Vol 11. Marcel. Dekker Series
- & 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.

ORIECTIVES

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 medicinal value. various nutraceuticals/herbs and theirhealth benefits 	anc
Drugs of marine origin	
Pharmacovigilance of drugs of natural origin	
THEORY 60 H	rs
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
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
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 12 features (Chemical nature, uses in pharmacy, medicinal and Hrs health benefits) of following.
 - a Carotenoids i) α and β Carotene ii) Xanthophyll (Lutein)
 - b) Limonoids i) d–Limonene ii) α Terpineol
 - d Saponins i) Shatavarins
 - flavonoids i) Resveratrol ii) Rutin iii) Hesperidin iv)
 Naringin v) Quercetin
 - Phenolic acids Ellagic acid

 - d Tocotrienols and Tocopherols
 - Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine. Taxol
 - Miscellaneous
- 5 Pharmacovigilance of drugs of natural origin: WHO and 12 AYUSH guidelines for safety monitoring of natural medicine, Hrs Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

REFERENCES (Latest Editions of)

- Pharmacognosy G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
- 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.
- Merbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
- 1. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
- 2 Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
- © Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.

- Matural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press. New York, 1998
- 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.
- 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 phytoconstituents

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

- l. Biosynthetic pathways and Radio tracing techniques: 12
 Constituents & their Biosynthesis, Isolation, Characterization and Hrs
 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
- Drug discovery and development: History of herbs as source of 12 drugs and drug discovery, the lead structure selection process, Hrs 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.
- 3 Extraction and Phytochemical studies: Recent advances in 12 extractions with emphasis on selection of method and choice of Hrs 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.

- 4 Phytochemical finger printing: HPTLC and LCMS/GCMS 12 applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.
- 5 Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) Hrs
 - a. Carvone, Citral, Menthol
 - b. Luteolin, Kaempferol
 - a 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.
- The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
- 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.

ORIECTIVES

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 12 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.
- Regulatory requirements for setting herbal drug industry: 12
 Global marketing management. Indian and international patent Hrs
 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.
- 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 12 clinical laboratory testing. Stability testing of natural products, Hrs protocols.
- Patents: Indian and international patent laws, proposed 12 amendments as applicable to herbal/natural products and Hrs 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.

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. Rangarl (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 105P)

- 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

ORIECTIVES

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, 12 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.
- Different tissue culture techniques: Organogenesis and 15 embryogenesis, synthetic seed and monoclonal variation, Hrs 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.
- 3 Immobilisation techniques & Secondary Metabolite 15
 Production: Immobilization techniques of plant cell and its Hrs 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.
- 4 Biotransformation and Transgenesis: Biotransformation, 13 bioreactors for pilot and large scale cultures of plant cells and Hrs 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.

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

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.
- 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

ORIECTIVES

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

- Herbal remedies Toxicity and Regulations: Herbals vs 12
 Conventional drugs, Efficacy of Herbal medicine products, Hrs Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues
- Adulteration and Deterioration: Introduction, Types of 12
 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
- 3 Ethnobotany and Ethnopharmacology: Ethnobotany in herbal 12 drug evaluation, Impact of Ethnobotany in traditional medicine, Hrs New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.
- 4 Analytical Profiles of herbal drugs: Andrographis paniculata, 12 Boswellia serata, Coleus forskholii, Curcuma longa, Embelica Hrs officinalis. Psoralea corvlifolia.
- 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.

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.
- 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. Rangarl, 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

- Fundamental concepts of Ayurveda, Siddha, Unani and 12
 Homoeopathy systems of medicine
 Hrs
 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).
- 2 Naturopathy, Yoga and Aromatherapy practices

12 Hrs

- Naturopathy Introduction, basic principles and treatment modalities.
- b) Yoga Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
- Aromatherapy Introduction, aroma oils for common problems, carrier oils.
- 3 Formulation development of various systems of medicine 12 Salient features of the techniques of preparation of some of the Hrs 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 - 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.

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

REFERENCES (Latest Editions of)

- 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.
- & 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.
- ${\tt 11.} \ \ Essential\ of\ Food\ and\ Nutrition,\ Swaminathan,\ Bappco,\ Bangalore.$
- 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.

12

Hrs

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

- Introduction: Herbal/natural cosmetics, Classification & 12
 Economic aspects. Hrs
 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.
- Commonly used herbal cosmetics, raw materials, preservatives, 12 surfactants, humectants, oils, colors, and some functional herbs, Hrs preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.
- Herbal Cosmetics: Physiology and chemistry of skin and 12 pigmentation, hairs, scalp, lips and nail, Cleansing cream, Hrs 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
- 4 Cosmeceuticals of herbal and natural origin: Hair growth 12 formulations, Shampoos, Conditioners, Colorants & hair oils, Hrs Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.

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

REFERENCES (Latest Editions of)

- Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi
- 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 veast
- 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 care.