

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, Kolla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

Principal,
Maulana Azad
University of
Pharmacy & Allied
Health Sciences

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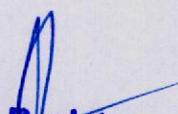
PHARMACY COUNCIL OF INDIA

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—


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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

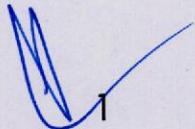
The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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


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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 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

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

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

| S. No. | Specialization | Code |
|--------|-----------------------------------|------|
| 1. | Pharmaceutics | MPH |
| 2. | Industrial Pharmacy | MIP |
| 3. | Pharmaceutical Chemistry | MPC |
| 4. | Pharmaceutical Analysis | MPA |
| 5. | Pharmaceutical Quality Assurance | MQA |
| 6. | Pharmaceutical Regulatory Affairs | MRA |
| 7. | Pharmaceutical Biotechnology | MPB |
| 8. | Pharmacy Practice | MPP |
| 9. | Pharmacology | MPL |
| 10. | Pharmacognosy | MPG |

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

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

| Course Code | Course | Credit Hours | Credit Points | Hrs./week | Marks |
|--------------------|--|--------------|---------------|-----------|-------|
| Semester I | | | | | |
| MPH101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MPH102T | Drug Delivery System | 4 | 4 | 4 | 100 |
| MPH103T | Modern Pharmaceutics | 4 | 4 | 4 | 100 |
| MPH104T | Regulatory Affair | 4 | 4 | 4 | 100 |
| MPH105P | Pharmaceutics Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPH201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 4 | 4 | 4 | 100 |
| MPH202T | Advanced Biopharmaceutics & Pharmacokinetics | 4 | 4 | 4 | 100 |
| MPH203T | Computer Aided Drug Delivery System | 4 | 4 | 4 | 100 |
| MPH204T | Cosmetic and Cosmeceuticals | 4 | 4 | 4 | 100 |
| MPH205P | Pharmaceutics Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |


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Table - 3: Course of study for M. Pharm. (Industrial Pharmacy)

| Course Code | Course | Credit Hours | Credit Points | Hrs./week | Marks |
|--------------------|--|--------------|---------------|-----------|-------|
| Semester I | | | | | |
| MIP101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MIP102T | Pharmaceutical Formulation Development | 4 | 4 | 4 | 100 |
| MIP103T | Novel drug delivery systems | 4 | 4 | 4 | 100 |
| MIP104T | Intellectual Property Rights | 4 | 4 | 4 | 100 |
| MIP105P | Industrial Pharmacy Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MIP201T | Advanced Biopharmaceutics and Pharmacokinetics | 4 | 4 | 4 | 100 |
| MIP202T | Scale up and Technology Transfer | 4 | 4 | 4 | 100 |
| MIP203T | Pharmaceutical Production Technology | 4 | 4 | 4 | 100 |
| MIP204T | Entrepreneurship Management | 4 | 4 | 4 | 100 |
| MIP205P | Industrial Pharmacy Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |


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Table - 4: Course of study for M. Pharm. (Pharmaceutical Chemistry)

| Course Code | Course | Credit Hours | Credit Points | Hrs./week | Marks |
|--------------------|---|--------------|---------------|-----------|-------|
| Semester I | | | | | |
| MPC101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MPC1012T | Advanced Organic Chemistry -I | 4 | 4 | 4 | 100 |
| MPC103T | Advanced Medicinal chemistry | 4 | 4 | 4 | 100 |
| MPC104T | Chemistry of Natural Products | 4 | 4 | 4 | 100 |
| MPC105P | Pharmaceutical Chemistry Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPC201T | Advanced Spectral Analysis | 4 | 4 | 4 | 100 |
| MPC202T | Advanced Organic Chemistry -II | 4 | 4 | 4 | 100 |
| MPC203T | Computer Aided Drug Design | 4 | 4 | 4 | 100 |
| MPC204T | Pharmaceutical Process Chemistry | 4 | 4 | 4 | 100 |
| MPC205P | Pharmaceutical Chemistry Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |


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Table - 5: Course of study for M. Pharm. (Pharmaceutical Analysis)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|--------------------|---|--------------|---------------|---------|-------|
| Semester I | | | | | |
| MPA101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MPA102T | Advanced Pharmaceutical Analysis | 4 | 4 | 4 | 100 |
| MPA103T | Pharmaceutical Validation | 4 | 4 | 4 | 100 |
| MPA104T | Food Analysis | 4 | 4 | 4 | 100 |
| MPA105P | Pharmaceutical Analysis Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPA201T | Advanced Instrumental Analysis | 4 | 4 | 4 | 100 |
| MPA202T | Modern Bio-Analytical Techniques | 4 | 4 | 4 | 100 |
| MPA203T | Quality Control and Quality Assurance | 4 | 4 | 4 | 100 |
| MPA204T | Herbal and Cosmetic Analysis | 4 | 4 | 4 | 100 |
| MPA205P | Pharmaceutical Analysis Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |


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Table - 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

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


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Table - 7: Course of study for M. Pharm. (Regulatory Affairs)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|--------------------|--|--------------|---------------|---------|-------|
| Semester I | | | | | |
| MRA 101T | Good Regulatory Practices | 4 | 4 | 4 | 100 |
| MRA 102T | Documentation and Regulatory Writing | 4 | 4 | 4 | 100 |
| MRA 103T | Clinical Research Regulations | 4 | 4 | 4 | 100 |
| MRA 104T | Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights | 4 | 4 | 4 | 100 |
| MRA 105P | Regulatory Affairs Practical I | 12 | 6 | 12 | 150 |
| | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | Total | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MRA 201T | Regulatory Aspects of Drugs & Cosmetics | 4 | 4 | 4 | 100 |
| MRA 202T | Regulatory Aspects of Herbal & Biologicals | 4 | 4 | 4 | 100 |
| MRA 203T | Regulatory Aspects of Medical Devices | 4 | 4 | 4 | 100 |
| MRA 204T | Regulatory Aspects of Food & Nutraceuticals | 4 | 4 | 4 | 100 |
| MRA 205P | Regulatory Affairs Practical II | 12 | 6 | 12 | 150 |
| | Seminar/Assignment | 7 | 4 | 7 | 100 |
| | Total | 35 | 26 | 35 | 650 |


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Table - 8: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

| Course Code | Course | Credit Hours | Credit Points | Hrs./week | Marks |
|--------------------|---|--------------|---------------|-----------|-------|
| Semester I | | | | | |
| MPB 101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MPB 102T | Microbial And Cellular Biology | 4 | 4 | 4 | 100 |
| MPB 103T | Bioprocess Engineering and Technology | 4 | 4 | 4 | 100 |
| MPB 104T | Advanced Pharmaceutical Biotechnology | 4 | 4 | 4 | 100 |
| MPB 105P | Pharmaceutical Biotechnology Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPB 201T | Proteins and protein Formulation | 4 | 4 | 4 | 100 |
| MPB 202T | Immunotechnology | 4 | 4 | 4 | 100 |
| MPB 203T | Bioinformatics and Computer Technology | 4 | 4 | 4 | 100 |
| MPB 204T | Biological Evaluation of Drug Therapy | 4 | 4 | 4 | 100 |
| MPB 205P | Pharmaceutical Biotechnology Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |


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Table - 9: Course of study for M. Pharm. (Pharmacy Practice)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|--------------------|---|--------------|---------------|---------|-------|
| Semester I | | | | | |
| MPP 101T | Clinical Pharmacy Practice | 4 | 4 | 4 | 100 |
| MPP 102T | Pharmacotherapeutics-I | 4 | 4 | 4 | 100 |
| MPP 103T | Hospital & Community Pharmacy | 4 | 4 | 4 | 100 |
| MPP 104T | Clinical Research | 4 | 4 | 4 | 100 |
| MPP 105P | Pharmacy Practice Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPP 201T | Principles of Quality Use of Medicines | 4 | 4 | 4 | 100 |
| MPP 102T | Pharmacotherapeutics II | 4 | 4 | 4 | 100 |
| MPP 203T | Clinical Pharmacokinetics and Therapeutic Drug Monitoring | 4 | 4 | 4 | 100 |
| MPP 204T | Pharmacoepidemiology & Pharmacoeconomics | 4 | 4 | 4 | 100 |
| MPP 205P | Pharmacy Practice Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |


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Table - 10: Course of study for (Pharmacology)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|--------------------|--|--------------|---------------|---------|-------|
| Semester I | | | | | |
| MPL 101T | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 4 | 100 |
| MPL 102T | Advanced Pharmacology-I | 4 | 4 | 4 | 100 |
| MPL 103T | Pharmacological and Toxicological Screening Methods-I | 4 | 4 | 4 | 100 |
| MPL 104T | Cellular and Molecular Pharmacology | 4 | 4 | 4 | 100 |
| MPL 105P | Pharmacology Practical I | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPL 201T | Advanced Pharmacology II | 4 | 4 | 4 | 100 |
| MPL 202T | Pharmacological and Toxicological Screening Methods-II | 4 | 4 | 4 | 100 |
| MPL 203T | Principles of Drug Discovery | 4 | 4 | 4 | 100 |
| MPL 204T | Experimental Pharmacology practical- II | 4 | 4 | 4 | 100 |
| MPL 205P | Pharmacology Practical II | 12 | 6 | 12 | 150 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |


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Table - 11: 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 |
| - | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester 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 |


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Table - 12: 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 - 13: 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 - 14: 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

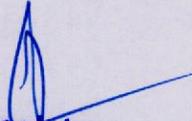

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Table - 15: Guidelines for Awarding Credit Points for Co-curricular Activities

| 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.

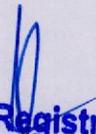
- iv. Communicating its recommendation to the Head of the institution on academic matters.
- v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table - 16.

11.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted 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.


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