## SECTION 1: REGULATIONS FOR THE M. PHARM DEGREE
## RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCE, KARNATAKA, ORDINANCE FOR THE GRADUATE COURSE LEADING MASTER'S DEGREE IN PHARMACY

### 1.1 ELIGIBILITY:

A candidate who has passed B. Pharm degree examination of Rajiv Gandhi University of Health Science, or B. Pharm Examination of any other recognized Indian University established by law in India or any other degree courses in Pharmacy recognized as equivalent by RGUHS or Pharmacy Council of India (PCI) and / or All India Council of Technical Education (A.I.C.T.E) for this purpose and who has secured not less than 55% of the maximum marks (aggregate of four years prescribed for the qualification examination shall be eligible for the admission to the M. Pharm course.

Further, Pharmacy teachers having recognized B. Pharm qualification and with minimum of five years of teaching experience in an institution approved by A.I.C.T.E and PCI will be eligible provided they have scored not less than 50% of the maximum marks (aggregate of four years in B. Pharm)

For SC/ST (Karnataka) Category-I candidates the prescribed percentage of marks will be 50% of the maximum marks in the qualifying examinations.

### 1.2 DURATION:

The course of study including submission of dissertation of the topic registered shall be of 24 months (two years) duration from the commencement of academic term.

The study of M. Pharm course shall be of annual system that includes M. Pharm part-I, extending for twelve months from the commencement of academic term and M. Pharm part-II of twelve months duration.

At the end of M. Pharm part-I, there shall be an university examination of M. Pharm Part-I. At the end of M. Pharm Part-II, the candidate shall submit a dissertation on the topic approved by the university.

### 1.3 COURSE OF STUDY

During the course of study, candidates of M. Pharm Part-I, shall undergo a compulsory course in Current Good Manufacturing Practices (cGMP) and Documentation, Pharmaceutical Validation, Quality Management systems, Pharmaceutical Regulatory Requirements in Drug regulatory affairs. The subject of Pharmacy Ethics shall be studied by candidates belonging to all branches. The syllabus for Pharmacy Ethics is given in Section V. There shall be three specialized subjects in each branch of M. Pharm course in addition to the common subject mentioned earlier.. The subjects for study under Drug regulatory affairs specialization are listed in the Table II.

**Table-1:** M. Pharm in Drug regulatory affairs

| | |
|---|---|
| 1 | Drug regulatory affairs |

Table II: Subjects to be studied in Drug regulatory affairs

| Sl.No | Branch | Paper | Name of subject |
|---|---|---|---|
| 1 | Drug Regulatory Affairs | I | Current Good Manufacturing Practices (cGMP) and Documentation |
| | | II | Pharmaceutical Validation |
| | | III | Quality Management systems |
| | | IV | Pharmaceutical Regulatory Requirements |

## 1.4 Attendance and Monitoring Process of Studies

**Attendance:**

**i.** A candidate pursuing M. Pharm course shall study in the concerned department of the institution for the entire period as full time student. No. candidate is permitted to work in any laboratory / college /industry/pharmacy, etc., while studying postgraduate course. No candidate should join any other course of study or appear for any other examination conducted by this university or any other university in India or abroad during the period of registration

**ii.** Each year shall be taken as a unity for the purpose of calculating attendance.

**iii.** Every student shall attend symposia, seminars, conferences, journal review meetings and lectures during each year as prescribed by the department/college/university and not absent him/her without valid reasons.

**iv.** Candidate who has put in a minimum of 80% of attendance in theory and practical assignments separately shall be permitted to appear for M. Pharm part-I examination.

**v.** Candidate who has put in a minimum of 80% of attendance in M. Pharm part-II shall only be eligible to submit the dissertation.

**vi.** Any student who fails to complete the course in the manner stated above shall not be permitted to appear for the University examinations.

**Monitoring Progress of Studies**

Every candidate hall maintain a work diary and record of his/her participation in the training programmes conducted by the department such as journal reviews, seminars, etc. (please see Chapter IV for model checklists and logbook specimen copy). The work diary shall be scrutinized and certified by the Head of the Department and Head of the Institution, and presented in the University practical examination if called for. Special mention may be made of the presentations by the candidate as well as details of experiments or laboratory procedures, conducted by the candidate. The presentations will be assessed by the faculty members and peers using relevant checklists given in the Section IV.

## 1.5 EXAMINATION

There shall be an examination for M. Pharm part-I at the end of on academic year for M. pharm part-II, the examination shall be an evaluation of dissertation and Viva-Voce at the end of twelve months (one Year) after commencement of M. Pharm Part-II course.

## 1.6 SCHEME OF EXAMINATION

**A. Sessional Examination:**

There shall be minimum of two sessional examinations in each subject of specialization conducted by the colleges at regular interval at the end of First term and Second term respectively both in theory and in practical which include seminars.

The sessional marks shall be awarded out of a maximum of 50 for theory and practical as follows:

| | **Theory** | | | **Practical** | |
|---|---|---|---|---|---|
| a) | Written examination (average of two) | 30 marks | a) | Practical Examination (average of two) | 30 marks |
| b) | Seminar | 20 Marks | b) | Lab work | 20 marks |
| | **Total Marks** | **50 marks** | | **Total Marks** | **50 Marks** |

**B. University Examination** ( M. Pharm Part-I)

There shall be two university examinations annually conducted at an interval of not less than four months. There shall be four theory papers in the university examination. Each theory paper shall be

of 3 hours duration carrying 100 marks each. In each paper, there shall be two log essay questions of 20 marks each, five short essay questions of ten marks each and two short notes of five marks each. Zone of the short not questions would be on Pharmacy Ethics in Paper I. The particulars of marks of Papers I, II, III and IV for all the branches are given in Table-III.

There shall be four practical examinations in all the respective branches. The duration of each practical examination is of six hours which carries 100 marks each.

**C. Criteria for Pass**

**M. Pharm Part-I**

A candidate who secures 50% of marks in each subject in theory and practical separately including sessional marks and university examination marks together shall be declared to have passé in M. Pharm part-I examination, provided the candidate secures a minimum of 40% marks (excluding sessionals) in theory & practical separately. Candidate, who fails in theory or practical exam kin a subject, shall appear for both theory and practical in the subsequent examination in the subject.

Those candidates who fail in one or more subjects shall have to appear only in the subjects so failed, in the subsequent examinations.

**Re-sessional examination:**

Candidates who want to improve their sessional marks may be permitted to take re-sessional examination after the announcement of results only once in one or more theory/practical papers. In respect of practical re-sessional, the marks, scored by the candidate, earlier in the laboratory work remains unchanged (out of 20 marks).

Candidtate who fail in M. Pharm part-I examination shall be permitted to continue M. Pharm part-II course. However, such candidate shall not be permitted to submit the dissertation unless the candidate completes M. Pharm part-I examination and passes both theory and practical at a time together.

**M. Pharm. Part -II**

Dissertation

i. Every candidate pursuing M. Pham course is required to carry out work on a selected research project under the guidance of a recognized postgraduate teacher. The results of such work shall be submitted in the form of a dissertation.
ii. The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions.
iii. The dissertation should be writer under the following headings
    1. Introduction
    2. Aims or Objectives of study
    3. Review of Literature
    4. Material and Methods
    5. Results
    6. Discussion
    7. Conclusion
    8. Summary
    9. References
    10. Tables
    11. Annexure

iv. The written text dissertation shall be not less than 50 pages shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed with double line spacing on one side of the bond paper (A 4 size 8. 27" x 11.69) and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-co guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least two month before the end of M. Pharm part II term.

v. A guide shall be a full time post graduate teacher of an institution affiliated to RGUHS and recognized by RGUHS as a guide for supervision of dissertation work. However a co guide can be opted wherever required. The co-guide shall also be a postgraduate teacher recognized by RGUHS as guide.

vi. **Synopsis**. A candidate shall submit synopsis to the Registrar, RGUHS of the intended project work through the guide, HOD and Head of the institutions, not later than nine months from the date of admission to M. Pharm part I on or before the date specified by RGUHS.

**1.6. SUBMISSION OF DISSERTATION:**

Three copied of the dissertation duly certified by the Guide, Head of the Department and the Principal shall be submitted to the Register , evaluation, RGUHS, through the principal two months before the final examination notified by RGUHS.

**1.7. VIVA-VOCE EXAMINATION:**

The Viva-Voce examination shall aim at assessing the depth of knowledge, logical reasoning, confidence and oral communication skills.

The Viva Voce examination shall be held after the submission of dissertation. If any candidate fails to submit the dissertation on or before the date prescribed, him/her Viva Voce shall be conducted during the subsequent examination which shall not be earlier than six months from the date fixed in the first instance.

**Examiners:** There shall be at least two examiners in each branch / specialization, out of them one shall be external examiner and the other one shall be the internal examiner. The internal examiner ordinarily be the guide. The qualification and teaching experience for appointment as examiner shall be as given in section No. 1.12

**a. DISTRIBUTION OF MARKS FOR M. PHARM PART-II EXAMINATION**

Total 200 marks, Dissertation-150 marks, and Viva Voce-50 marks.

The dissertation viva voce shall be valued, by the examiners together appointed by the university.

Scheme of evaluation of M. Pharm. Dissertation

The minimum marks for pass in M. Pharm part II shall be 50% of the marks of dissertation and viva and an aggregate of 100 marks out of 200 marks.

1.9 Class shall be declared on the basis of the aggregate of marks scored in M. Pharm Part I and part II as follows:

| | |
|---|---|
| (1) 75% and above | - Distinction |
| (2) 60% & above but less than 75% | - First class |
| (3) 50% & above but less than 60% | -Second class |

1.10 The candidate shall not take more than double the number of years prescribed for the course (i.e., 4 years) for passing. Otherwise the candidate should seek readmission.

**TABLE III:** Drug Regulatory Affairs

| Theory | | | | | | Practical | | | |
|---|---|---|---|---|---|---|---|---|---|
| Subjects | No of papers | Duration of paper (Hours) | Maximum marks for written exam | Sessional maximum marks | Total | Duration of paper (Hours) | Maximum marks for written exam | Sessional maximum marks | Total |
| Paper I Current Good Manufacturing Practices cGMP) and Documentation | 1 | 3 | 100 | 50 | 150 | 6 | 100 | 50 | 150 |
| Paper II | 1 | 3 | 100 | 50 | 150 | 6 | 100 | 50 | 150 |
| Paper III | 1 | 3 | 100 | 50 | 150 | 6 | 100 | 50 | 150 |
| Paper IV | 1 | 3 | 100 | 50 | 150 | 6 | 100 | 50 | 150 |
| Total | | | | | 600 | | | | 600 |

Table IV: Consolidated Marks for Part I & Part II

| Part I | Part II | Grand Total |
|---|---|---|
| 1200 | 200 | 1400 |

**1.11. M Pharm Qualification required to Teacher of Drug Regulatory affairs**

| Sl No | Name of the subject | M Pharm Qualification |
|---|---|---|
| 1 | Drug Regulatory Affairs | Any M Pharm with 6 six years experince |

**1.12 Qualification and experience required for postgraduate Teacher, Guide and Examiner:**

**Qualification and experience required for teaching M. Pharm**

M. Pharm with a minimum of five years teaching experience for B. Pharm degree course after obtaining M. Pharm degree. He/she should have taught the subjects of his/her PG any specialization

OR

M. Pharm the subject of specialization concerned and Ph. D with one year teaching experience for B. Pharm degree course in any specialization

OR

One year research experience or Pot Doctoral Experience after Ph. D course in Pharmacy after obtaining M. Pharm degree

**B. qualification and experience required to be a PG guide**

He /She shall be M. Pharm with minimum of Six years of teaching experience for B. Pharm degree course out of which two years teaching experience of PG course in Pharmacy after obtaining M. Pharm degree.

**OR**

He / She shall be M. Pharm with minimum of Six years of teaching experience in B. Pharm and should have published at least two peer reviewed papers in scientific journals of Pharmacy or allied branches as first or second author.

OR

M. Pharm in any specialization and Ph. D with two years teaching experience for B. Pharm or PG Pharm course in the any specialization.

**Number of candidates per guide**

An approved post graduate guide can guide a maximum of Five M. Pharm students in one academic year,

**Examiner**

To be eligible to become PG examiner, he / she should have been a recognized as a PG guide in Pharmacy by RGUHS for a t least two years.

**1.13 Co-guide**

The qualification and expericen required for a co-guide is the same as that prescribed for a PG guide (sec1.14B) However,

i. For the subject of Industrial pharmacy, the qualification and experience required for a person working in a pharmaceutical industry to be appointed as co-guide shall be M. Pharm or Ph. D degree from a recognized university established by law and at least 10 years of experience in manufacturing or in R & D quality control in a reputed pharmaceutical industry recognized by DST.

ii. For the subject of Pharmacy Practice, the requirement for a co-guide is that he she should be a recognized PG teacher of RGUHS belonging to any faculty of health sciences from any affiliated colleges having approved postgraduate courses.

**A. Co guide can guide a maximum of two students at a time.**