ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

M – PHARMACY (INDUSTRIAL PHARMACY)

FOR
M.PHARMACY TWO YEAR PG COURSE
(Applicable for the batches admitted from 2018-2019)

SCHOOL OF PHARMACY
ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)
Venkatapur, Ghatkesar, Hyderabad – 500088

R 18 - ACADEMICREGULATIONS (CBCS) FOR M. Pharm. (REGULAR) DEGREE PROGRAMMES

Applicable for the students of M. Pharm. (Regular) programme from the Academic Year ***2018-19*** and onwards

The M.Pharm. Degree of Jawaharlal Nehru Technological University Hyderabad shall be conferred on candidates who are admitted to the programme and who fulfill all the requirements for the award of the Degree.

1.0 ELIGIBILITY FOR ADMISSIONS

Admission to the above programme shall be made subject to eligibility, qualification and specialization as prescribed by the University from time to time.

Admissions shall be made on the basis of merit/rank obtained by the candidates at the qualifying Entrance Test conducted by the University or on the basis of any other order of merit as approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.0 AWARD OF M.Pharm. DEGREE

2.1 A student shall be declared eligible for the award of the M.Pharm. Degree, if he pursues a course of study in not less than two and not more than four academic years, failing which he shall forfeit his seat in M.Pharm. programme.

2.2 The student shall register for all 88 credits and secure all the 88 credits.

2.3 The minimum instruction days in each semester are 90.

3.0 COURSES OF STUDY

The following specializations are offered at present for the M.Pharm. programme of study.

1. Industrial Pharmacy
2. Pharmaceutics
3. Pharmacology
4. Pharmaceutical Analysis and Quality Assurance

4 Course Registration

4.1 A 'Faculty Advisor or Counselor' shall be assigned to each student, who will advise him on the Post Graduate Programme (PGP), its Course Structure and Curriculum, Choice/Option for Subjects/ Courses, based on his competence, progress, pre-requisites and interest.

4.2 Academic Section of the College invites 'Registration Forms' from students with in 15 days from the commencement of class work through 'ON-LINE SUBMISSIONS', ensuring 'DATE and TIME Stamping'. The ON-LINE Registration Requests for any 'CURRENT SEMESTER' shall be completed BEFORE the commencement of SEEs (Semester End Examinations) of the 'PRECEDING SEMESTER'.

4.3 A Student can apply for ON-LINE Registration, ONLY AFTER obtaining the 'WRITTEN APPROVAL' from his Faculty Advisor, which should be submitted to the College Academic Section through the Head of Department (a copy of it being retained with Head of Department, Faculty Advisor and the Student).

4.4 If the Student submits ambiguous choices or multiple options or erroneous entries - during ON-LINE Registration for the Subject(s) / Course(s) under a given/ specified Course Group/ Category as listed in the Course Structure, only the first mentioned Subject/ Course in that Category will be taken into consideration.

4.5 Subject/ Course Options exercised through ON-LINE Registration are final and CANNOT be changed, nor can they be inter-changed; further, alternate choices will also not be considered. However, if the Subject/ Course that has already been listed for Registration (by the Head of Department) in a Semester could not be offered due to any unforeseen or unexpected reasons, then the Student shall be allowed to have alternate choice - either for a new Subject (subject to offering of such a Subject), or for another existing Subject (subject to availability of seats), which may be considered. Such alternate arrangements will be made by the Head of Department, with due notification and time-framed schedule, within the FIRST WEEK from the commencement of Class-work for that Semester.

5 <u>ATTENDANCE</u>

The programmes are offered on a unit basis with each subject being considered a unit.

5.1 Attendance in all classes (Lectures/Laboratories etc.) is compulsory. The minimum required attendance in each theory / Laboratory etc. is 75% including the days of attendance in sports, games, NCC and NSS activities for appearing for the End Semester examination. A student shall not be permitted to appear for the Semester End Examinations (SEE) if attendance is less than 75%.

5.2 Condonation of shortage of attendance in each subject up to 10% (65% and above and below75%) in each semester shall be granted by the College Academic Committee on genuine medical grounds and valid reasons on representation by the candidate with supporting evidence.

5.3 Shortage of Attendance below 65% in each subject shall not be condoned.

5.4 Students whose shortage of attendance is not condoned in any subject are not eligible to write their end semester examination of that subject and their registration shall stand cancelled.

5.5 A prescribed fees hall be payable towards condonation of shortage of attendance.

5.6 A candidate shall get minimum required attendance at least in three (3) theory subjects in the present semester to get promoted to the next semester. In order to qualify for the award of the M.Pharm. Degree, the candidate shall complete all the academic requirements of the subjects, as per the course structure.

5.7 A student shall not be promoted to the next semester unless he satisfies the attendance requirement of the present Semester, as applicable. They may seek readmission into that semester when offered next. If any candidate fulfills the attendance requirement in the present semester, he shall not be eligible for readmission in to the same class.

6 EVALUATION

The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks for theory and 100 marks for practical, on the basis of Internal Evaluation and End Semester Examination.

6.1 For the theory subjects 75 marks shall be awarded for the performance in the Semester End Examination and 25 marks shall be awarded for Continuous Internal Evaluation (CIE). The Continuous Internal Evaluation shall be made based on the average of the marks secured in the two Mid Term-Examinations conducted, one in the middle of the Semester and the other, immediately after the completion of Semester instructions. Each mid-term examination shall be conducted for a total duration of 120 minutes with Part A as compulsory question (10 marks) consisting of 5 sub-questions carrying 2 marks each, and Part B with 3 questions to be answered out of 5 questions, each question carrying 5 marks.

There shall be an optional third midterm examination during the preparation cum external practical examinations period subject to the following.

i. Interested students have to register for the third mid examination by paying prescribed registration fee.
ii. Third midterm examination covers entire semester syllabus carrying 25 marks. The average of best two midterm examinations shall be taken as the final marks secured by each candidate**.** If he/she is absent for any test, he/she shall be awarded zero marks for that test.

The details of the Question Paper pattern for End Examination (Theory) are given below:

- The Semester End Examination will be conducted for 75 marks. It consists of two parts. i) Part-A for 25 marks, ii) Part-B for 50 marks.

- Part-A is a compulsory question consisting of 5 questions, one from each unit and carries 5 marks each.

- Part-B to be answered 5 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

6.2 For practical subjects, 75 marks shall be awarded for performance in the Semester End Examinations and 25 marks shall be awarded for day-to-day performance as Internal Marks.

6.3 The practical end semester examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed by the Principal from the panel of examiners recommended by Chairman, Board of Studies in respective Branches.

6.4 There shall be two seminar presentations during I year I semester and II semester. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report form and shall make an oral presentation before the Departmental Academic Committee consisting of Head of the Department, Supervisor and two other senior faculty members of the department. For each Seminar there will be only internal evaluation of 100 marks. A candidate has to secure a minimum of 50% of marks to be declared successful. If he fails to fulfill minimum marks, he has to reappear during the supplementary examinations.

6.5 There shall be a Comprehensive Viva-Voce in II year I Semester. The Comprehensive Viva-Voce is intended to assess the students' understanding of various subjects he has studied during the M.Pharm. course of study. The Head of the Department shall be associated with the conduct of the Comprehensive Viva-Voce through a Committee. The Committee consisting of Head of the Department, one senior faculty member and an external examiner. The external examiner shall be appointed by the Principal from the panel of 3 examiners recommended by Chairman, Board of Studies in respective Branches. There are no internal marks for the Comprehensive Viva-Voce and evaluates for maximum of 100 marks. A candidate has to secure a minimum of 50% of marks to be declared successful. If he fails to fulfill minimum marks, he has to reappear during the supplementary examinations.

6.6 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the Semester End Examination and a minimum aggregate of 50% of the total marks in the Semester End Examination and Continuous Internal Evaluation taken together.

6.7 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 6.6) he has to reappear for the Semester End Examination in that subject.

6.8 A candidate shall be given one chance to re-register for the subjects if the internal marks

secured by a candidate is less than 50% and failed in that subject for maximum of two subjects and should register within four weeks of commencement of the class work. In such a case, the candidate must re-register for the subjects and secure the required minimum attendance. The candidate's attendance in the re-registered subject(s) shall be calculated separately to decide upon his eligibility for writing the Semester End Examination in those subjects. In the event of the student taking another chance, his Continuous Internal Evaluation (internal) marks and Semester End Examination marks obtained in the previous attempt stands cancelled.

6.9 In case the candidate secures less than the required attendance in any subject, he shall not be permitted to write the Semester End Examination in that subject. He shall re-register for the subject when next offered.

7 Examinations and Assessment - The Grading System

7.1 Marks will be awarded to indicate the performance of each student in each Theory Subject, or Lab/Practicals, or Seminar, or Project, etc., based on the % marks obtained in CIE + SEE (Continuous Internal Evaluation + Semester End Examination, both taken together) as specified in Item 6 above, and a corresponding Letter Grade shall be given.

7.2 As a measure of the student's performance, a 10-point Absolute Grading System using the following Letter Grades (UGC Guidelines) and corresponding percentage of marks shall be followed:

% of Marks Secured (Class Intervals)	Letter Grade (UGC Guidelines)	Grade Points
90% and above ($\geq 90\%, \leq 100\%$)	O (Outstanding)	10
Below 90% but not less than 80% ($\geq 80\%, < 90\%$)	**A**$^{+}$ (Excellent)	9
Below 80% but not less than 70% ($\geq 70\%, < 80\%$)	**A** (Very Good)	8
Below 70% but not less than 60% ($\geq 60\%, < 70\%$)	**B**$^{+}$ (Good)	7
Below 60% but not less than 50% ($\geq 50\%, < 60\%$)	**B** (Above Average)	6
Below 50% ($< 50\%$)	F (Fail)	0
Absent	Ab	0

7.3 A student obtaining F Grade in any Subject shall be considered 'failed' and is be required to reappear as 'Supplementary Candidate' in the Semester End

Examination (SEE), as and when offered. In such cases, his Internal Marks (CIE Marks) in those Subjects will remain the same as those he obtained earlier.

7.4 A student not appeared for examination then 'Ab' Grade will be allocated in any Subject shall be considered 'failed' and will be required to reappear as 'Supplementary Candidate' in the Semester End Examination (SEE), as and when offered.

7.5 A Letter Grade does not imply any specific Marks percentage and it will be the range of marks percentage.

7.6 In general, a student shall not be permitted to repeat any Subject/ Course (s) only for the sake of 'Grade Improvement' or 'SGPA/ CGPA Improvement'.

7.7 A student earns Grade Point (GP) in each Subject/ Course, on the basis of the Letter Grade obtained by him in that Subject/ Course. The corresponding 'Credit Points' (CP) are computed by multiplying the Grade Point with Credits for that particular Subject/ Course.

Credit Points (CP) = Grade Point (GP) x Credits …. For a Course

7.8 The Student passes the Subject/ Course only when he **gets GP $\geq$ 6(B Grade or above).**

7.9 The Semester Grade Point Average (SGPA) is calculated by dividing the Sum of Credit Points (ΣCP) secured from ALL Subjects/ Courses registered in a Semester, by the Total Number of Credits registered during that Semester. SGPA is rounded off to TWO Decimal Places. SGPA is thus computed as

SGPA = $\left\{\sum_{i=1}^{N} C_i G_i\right\} / \left\{\sum_{i=1}^{N} C_i\right\}$ **For each Semester**,

where 'i' is the Subject indicator index (takes into account all Subjects in a Semester), 'N' is the no. of Subjects 'REGISTERED' for the Semester (as specifically required and listed under the Course Structure of the parent Department), C is the no. of Credits allotted to the ith Subject, and G represents the Grade Points (GP) corresponding to the Letter Grade awarded for that i^{th} Subject.

7.10 The Cumulative Grade Point Average (CGPA) is a measure of the overall cumulative performance of a student over all Semesters considered for registration. The CGPA is the ratio of the Total Credit Points secured by a student in ALL registered Courses in ALL Semesters, and the Total Number of Credits registered in ALL the Semesters. CGPA is rounded off to TWO Decimal Places. CGPA is thus computed from the I Year Second Semester onwards, at the end of each Semester, as per the formula

CGPA = $\left\{\sum_{j=1}^{M} C_j G_j\right\} / \left\{\sum_{j=1}^{M} Cj\right\}$ **… for all S Semesters registered**

(ie., upto and inclusive of S Semesters, $S \geq 2$**)**,

where 'M' is the TOTAL no. of Subjects (as specifically required and listed under the Course Structure of the parent Department) the Student has 'REGISTERED' from the 1st Semester onwards upto and inclusive of the Semester S (obviously M > N), 'j' is the Subject indicator index (takes into account all Subjects from 1 to S Semesters), C is the no. of Credits allotted to the jth Subject, and G represents the Grade Points (GP) corresponding to the Letter Grade awarded for that jth Subject. After registration and completion of I Year I Semester however, the SGPA of that Semester itself may be taken as the CGPA, as there are no cumulative effects.

7.11 For Calculations listed in Item 7.6 – 7.10, performance in failed Subjects/ Courses (securing F Grade) will also be taken into account, and the Credits of such Subjects/ Courses will also be included in the multiplications and summations.

8. EVALUATION OF PROJECT/DISSERTATION WORK

Every candidate shall be required to submit a thesis or dissertation on a topic approved by the Project Review Committee.

8.1 A Project Review Committee (PRC) shall be constituted with Head of the Department as Chairperson, Project Supervisor and one senior faculty member of the Departments offering the M.Pharm. Programme.

8.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects, both theory and practical.

8.3 After satisfying 8.2, a candidate has to submit, in consultation with his Project Supervisor, the title, objective and plan of action of his project work to the PRC for approval. Only after obtaining the approval of the PRC the student can initiate the Project work.

8.4 If a candidate wishes to change his supervisor or topic of the project, he can do so with the approval of the PRC. However, the PRC shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of project proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

8.5 A candidate shall submit his project status report in two stages at least with a gap of 3 months between them.

8.6 The work on the project shall be initiated at the beginning of the II year and the duration of the project is two semesters. A candidate is permitted to submit Project Thesis only after successful completion of all theory and practical courses with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. For the approval of PRC the candidate shall submit the draft copy of thesis to the Head of the Department and make an oral presentation before the PRC.

8.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College/School/Institute.

8.8 For Project work **Review I** in II Year I Sem. there is an internal marks of 100, the evaluation should be done by the PRC for 50 marks and Supervisor will evaluate for 50 marks. The Supervisor and PRC will examine the Problem Definition, Objectives, Scope of Work, Literature Survey in the same domain. A candidate has to secure a minimum of 50% of marks to be declared successful for Project Work Review I. If he fails to fulfill minimum marks, he has to reappear as per the recommendations of the PRC.

8.9 For Project work **Review II** in II Year II Sem. there is an internal marks of 100, the evaluation should be done by the PRC for 50 marks and Supervisor will evaluate for 50 marks. The PRC will examine the overall progress of the Project Work and decide the Project is eligible for final submission or not. A candidate has to secure a minimum of 50% of marks to be declared successful for Project Work Review II. If he fails to fulfill minimum marks, he has to reappear as per the recommendations of the PRC.

8.10 After approval from the PRC, a soft copy of the thesis should be submitted for ANTI-PLAGIARISM check and the plagiarism report should be submitted to the examination branch and be included in the final thesis. The thesis will be accepted for submission, if the similarity index is less than **30%.** If the similarity index has more than the required percentage, the student is advised to modify accordingly and re-submit the soft copy of the thesis after one month. The maximum number of re-submissions of thesis after plagiarism check is limited to TWO. The candidate has to register for the project work and work for two semesters. After attempts, the admission is liable to be cancelled. The college authorities are advised to make plagiarism check of every soft copy of thesis before submissions.

8.11 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College, after submission of a research paper related to the project work in a UGC approved journal. A copy of the submitted research paper shall be attached to thesis.

8.12 For Project Evaluation (Viva Voce) in II Year II Sem. there is an external mark of 100 and the same evaluated by the External examiner appointed by the Institution. The candidate has to secure minimum of 50% marks in Project Evaluation (Viva-Voce) examination.

8.13 If he fails to fulfill as specified in 8.12, he will reappear for the Viva-Voce examination only after three months. In the reappeared examination also, fails to fulfill, he will not be eligible for the award of the degree.

8.14 The thesis shall be adjudicated by one examiner selected by the Institution. For this, Chairmen, BOS of the respective departments shall submit a panel of 3 examiners, who are eminent in that field with the help of the concerned guide and senior faculty of the department.

8.15 If the report of the examiner is not favourable, the candidate shall revise and resubmit the Thesis. If the report of the examiner is un favourable again, the thesis shall be summarily rejected.

8.16 If the report of the examiner is favourable, Project Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the

external examiner who adjudicated the Thesis.

8.17 The Head of the Department shall coordinate and make arrangements for the conduct of Project Viva- Voce examination.

9. AWARD OF DEGREE AND CLASS

9.1 A Student who registers for all the specified Subjects/ Courses as listed in the Course Structure, satisfies all the Course Requirements, and passes the examinations prescribed in the entire PG Programme (PGP), and secures the required number of Credits 88 (with CGPA ≥ 6.0), shall be declared to have 'QUALIFIED' for the award of the M.Pharm. Degree in the chosen Branch of Engineering and Technology with specialization as he admitted.

9.2 **Award of Class**

After a student has satisfied the requirements prescribed for the completion of the programme and is eligible for the award of M.Pharm. Degree, he shall be placed in one of the following three classes based on the CGPA:

Class Awarded	CGPA
First Class with Distinction	≥ 7.75
First Class	6.75≤CGPA < 7.75
Second Class	6.00≤CGPA < 6.75

9.3 A student with final CGPA (at the end of the PGP) < 6.00 will not be eligible for the Award of Degree.

10. WITHHOLDING OF RESULTS

If the student has not paid the dues, if any, to the institution or if any case of indiscipline is pending against him, the result of the student will be withheld and he will not be allowed into the next semester. His degree will be withheld in such cases.

11. TRANSITORY REGULATIONS

11.1 If any candidate is detained due to shortage of attendance in one or more subjects, they are eligible for re-registration to maximum of two earlier or equivalent subjects at a time as and when offered.

11.2 The candidate who fails in any subject will be given two chances to pass the same subject; otherwise, he has to identify an equivalent subject as per R18 Academic Regulations.

12 GENERAL

12.1 **Credit**: A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field

work per week.

12.2 **Credit Point:** It is the product of grade point and number of credits for a course.

12.3 Wherever the words “he”, “him”, “his”, occur in the regulations, they include “she”, “her”.

12.4 The academic regulation should be read as a whole for the purpose of any interpretation.

12.5 In the case of any doubt or ambiguity in the interpretation of the above rules, the Decision of the Academic Council is final.

12.6 The Academic Council may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the Academic Council.

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, cell phones, pager, palm, computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The hall ticket of the candidate is to be cancelled and sent to the controller of examinations, AGI.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination(including practical's

		and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all semester examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all semester examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
6.	Refuses to obey the orders of the Chief Superintendent/Assistant-Superintendent/ any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in-charge or any person on duty in or outside the examination hall of any injury to his person or to any office relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations,	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subjects and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders. They will be handed over to the police and a police case is registered against them.

	or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the college campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all semester examinations. The continuation of the course by the candidate is subject to the academic regulation in connection with forfeiture of seat.
8.	Posses any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with college indulges in any malpractice or improper conduct mentioned in clause 6 to 8	Student of the college's expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeiture the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.

10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of the semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the Malpractices committee, AGI for further action to award suitable punishment.	

ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)
M. PHARM. (INDUSTRIAL PHARMACY)
(R18) COURSE STRUCTURE AND SYLLABUS

I YEAR I SEMESTER

Code	Group	Subject	Hrs/Wk	Credits
	Theory	Modern Pharmaceutical Analytical Techniques	4	4
	Theory	Pharmaceutical Formulation Development	4	4
	Theory	Novel Drug Delivery Systems	4	4
	Theory	Intellectual Property Rights	4	4
	Lab	Industrial Pharmacy Practical I	12	6
	-	Seminar/Assignment	7	4
		Total Credits	**35**	**26**

I YEAR II SEMESTER

Code	Group	Subject	Hrs/Wk	Credits
	Theory	Advanced Biopharmaceutics & Pharmacokinetics	4	4
	Theory	Scale Up and Technology Transfer	4	4
	Theory	Pharmaceutical Production Technology	4	4
	Theory	Entrepreneurship Management	4	4
	Theory	Research Methodology and Biostatistics	4	4
	Lab	Industrial Pharmacy Practical II	12	6
	-	Seminar/Assignment	7	4
		Total Credits	**39**	**30**

II YEAR - I Semester

Code	Group	Subject	Hrs/Wk	Credits
		Comprehensive Viva-Voce	--	4
		Project work Review I	24	12
		Total Credits	**24**	**16**

II YEAR - II Semester

Code	Group	Subject	Hrs/Wk	Credits
		Project work Review II	8	4
		Project Evaluation(Viva-Voce)	16	12
		Total Credits	**24**	**16**

ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)

M.Pharmacy I year I Sem. **T/P C**
4/- 4

(MIP101T) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

60 Hours

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,

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

UNIT-I **11 Hours**

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

b) **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data interpretation.

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

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

UNIT-II **11 Hours**

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.

UNIT-III **11 Hours**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT-IV **11 Hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drugs from excipients, data interpretation and applications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) High Performance Thin Layer chromatography
d) Ion exchange chromatography
e) Column chromatography
f) Gas chromatography
g) High Performance Liquid chromatography
h) Ultra High Performance Liquid chromatography
g) Affinity chromatography
h) Gel Chromatography

UNIT-V **16 Hours**

a) **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
i) Paper electrophoresis
ii) Gel electrophoresis
iii) Capillary electrophoresis
iv) Zone electrophoresis
v) Moving boundary electrophoresis
vi) Iso electric focusing
b) **X ray Crystallography**: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.
c) **Immunological assays**: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ANURAG GROUP OF INSTITUTIONS

(AUTONOMOUS)

M.Pharmacy I year I Sem. **T/P C**

4/- 4

(MIP 102T) PHARMACEUTICAL FORMULATION DEVELOPMENT

60 Hours

SCOPE

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

OBJECTIVES

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

1. The scheduled activities in a Pharmaceutical firm.
2. The pre formulation studies of pilot batches of pharmaceutical industry.
3. The significance of dissolution and product stability

UNIT-I **12Hrs**

Preformulation Studies: Molecular optimization of APIs (drugsubstances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT-II **12Hrs**

Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

UNIT-III **12Hrs**

Solubility: Importance, experimental determination, phase solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

UNIT-IV **12Hrs**

Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations.

UNIT-V **12Hrs**

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

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M.Pharmacy I year I Sem. **T/P C**

4/- 4

(MPH 103T) NOVEL DRUG DELIVERY SYSTEMS

60 Hours

SCOPE

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems..

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

1. The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
2. To formulate and evaluate various novel drug delivery systems.

UNIT-I **12Hrs**

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for Drug Delivery: Polymers / co-polymersintroduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

UNIT-II **20Hrs**

a) **Study of Various DDS**: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, and pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

b) **Transdermal Drug Delivery Systems**: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

UNIT-III **12Hrs**

Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

UNIT-IV **6Hrs**

a) Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

b) Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

UNIT-V **10Hrs**

a) **Sub Micron Cosmeceuticals**: Biology, formulation science andevaluation of various cosmetics for skin, hair, nail, eye etc and it'sregulatory aspects.

b) **New trends for Personalized Medicine**: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker,NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

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M.Pharmacy I year I Sem. **T/P C**

4/- 4

(MPH 104T) INTELLECTUAL PROPERTY RIGHTS

60 Hours

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs.

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

1. Assist in Regulatory Audit process.
2. Establish regulatory guidelines for drug and drug products
3. The Regulatory requirements for contract research organization

UNIT-I **12Hrs**

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

UNIT-II **12Hrs**

Role of GATT, TRIPS, and WIPO.

UNIT-III **12Hrs**

Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.

UNIT-IV **12Hrs**

Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA.

UNIT-V **12Hrs**

Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition.
2. Applied Production and Operation Management By Evans, Anderson and Williams.
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers.
4. ISO 9000-Norms and explanations.
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker.

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M.Pharmacy I year I Sem. **T/P C**

-/12 6

(MIP 105P) PHARMACEUTICS PRACTICAL I

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
3. Experiments based on HPLC / GC.
4. Estimation of riboflavin/quinine sulphate by flourimetry.
5. Estimation of sodium/potassium by flame photometry.
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation.
9. Stability studies of drugs in dosage forms at 25^{o}C, 60% RH and 40^{o}C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(MIP 201T) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

60 Hours

SCOPE

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

1. The basic concepts in Biopharmaceutics and pharmacokinetics.
2. The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. To critically evaluate Biopharmaceutics studies involving drug product equivalency.
4. To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

UNIT-I **12Hrs**

Drug absorption from the gastrointestinal tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), Ph Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT-II **12Hrs**

Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.

UNIT-III **12Hrs**

Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, the effect of tissue-binding interactions, Cytochrome P450-based drug interactions, and Drug interactions linked to transporters.

UNIT-IV **12Hrs**

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, the Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

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UNIT-V **12Hrs**

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., Vallab Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995.
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(MIP 202T) SCALE UP AND TECHNOLOGY TRANSFER

60 Hours

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

1. Manage the scale up process in pharmaceutical industry.
2. Assist in technology transfer.
3. To establish safety guidelines, which prevent industrial hazards.

UNIT-I **12Hrs**

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

UNIT-II **12Hrs**

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT-III **12Hrs**

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

UNIT-IV **12Hrs**

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT- V **12Hrs**

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.

6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli.

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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(MIP 203T) PHARMACEUTICAL PRODUCTION TECHNOLOGY

60 Hours

SCOPE

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production.

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

1. Handle the scheduled activities in a Pharmaceutical firm.
2. Manage the production of large batches of pharmaceutical formulations.

UNIT-I **12Hrs**

Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT-II **12Hrs**

Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

UNIT-III **12Hrs**

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

UNIT-IV **12Hrs**

Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

UNIT-V **12Hrs**

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.

3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

M.Pharmacy I year II Sem. **T/P C**

4/- 4

(MIP 204T) ENTERPRENEURSHIP MANAGEMENT

60 Hours

SCOPE

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

OBJECTIVES

On completion of this course it is expected that students will be able to understand,

1. The Role of enterprise in national and global economy
2. Dynamics of motivation and concepts of entrepreneurship
3. Demands and challenges of Growth Strategies and Networking

UNIT-I **12Hrs**

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT-II **12Hrs**

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT-III **12Hrs**

Launching and Organising an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT-IV **12Hrs**

Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT-V **12Hrs**

Preparing Project Proposal To Start On New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.

3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

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M.Pharmacy I year II Sem.	**L**	**T/P**	**C**
	4	**-/-**	**4**

(MRM 301T) RESEARCH METHODOLOGY AND BIOSTATICS

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

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

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(MIP 205P) INDUSTRIAL PHARMACY PRACTICAL II

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands.
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug.
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software.
6. In vitro cell studies for permeability and metabolism.
7. Formulation and evaluation of tablets.
8. Formulation and evaluation of capsules.
9. Formulation and evaluation of injections.
10. Formulation and evaluation of emulsion.
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.