ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

M – PHARMACY (PHARMACEUTICAL ANALYSIS)

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. (PHARMACEUTICAL ANALYSIS)
(R18) COURSE STRUCTURE AND SYLLABUS

I YEAR I SEMESTER

Code	Group	Subject	Hrs/Wk	Credits
	Theory	Modern Pharmaceutical Analytical Techniques	4	4
	Theory	Advanced Pharmaceutical Analysis	4	4
	Theory	Pharmaceutical Validation	4	4
	Theory	Food Analysis	4	4
	Lab	Pharmaceutical Analysis Practical I	12	6
	-	Seminar/Assignment	7	4
		Total Credits	**35**	**26**

I YEAR II SEMESTER

Code	Group	Subject	Hrs/Wk	Credits
	Theory	Advanced Instrumental Analysis	4	4
	Theory	Modern Bio-Analytical Techniques	4	4
	Theory	Quality Control & Quality Assurance	4	4
	Theory	Herbal and Cosmetic Analysis	4	4
	Theory	Research Methodology and Biostatistics	4	4
	Lab	Pharmaceutical Analysis 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

(MPA101T) 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

(MPA102T) ADVANCED PHARMACEUTICAL ANALYSIS

60 Hours

SCOPE

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

OBJECTIVES

Upon completion of the course, student shall able to know

1. Appropriate analytical skills required for the analytical method development.
2. Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
3. Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

UNIT-I **10Hrs**

Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.

Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products.

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

UNIT-II **10Hrs**

Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis.

Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations.

UNIT-III **10Hrs**

Impurity profiling and degradent characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products.

UNIT-IV **10Hrs**

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

UNIT-V **20Hrs**

Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thEdition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, JohnWiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

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

4/- 4

(MPA103T) PHARMACEUTICAL VALIDATION

60 Hours

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

OBJECTIVES

Upon completion of the course, student shall be able to

1. Explain the aspect of validation
2. Carryout validation of manufacturing processes
3. Apply the knowledge of validation to instruments and equipments
4. Validate the manufacturing facilities

UNIT-I **12Hrs**

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT-II **12Hrs**

Qualification of analytical instruments: Electronic balance, Ph meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT-III **12Hrs**

Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT-IV **12Hrs**

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

UNIT-V **12Hrs**

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism

for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

ANURAG GROUP OF INSTITUTIONS
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M.Pharmacy I year I Sem. **T/P C**

4/- 4

(MPA104T) FOOD ANALYSIS

60 Hours

SCOPE

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

OBJECTIVES

At completion of this course student shall be able to understand various analytical techniques in the determination of

1. Food constituents
2. Food additives
3. Finished food products
4. Pesticides in food
5. And also student shall have the knowledge on food regulations and legislations

UNIT-I **12Hrs**

Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates.

Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

UNIT-II **12Hrs**

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

UNIT-III **12Hrs**

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

UNIT-IV **12Hrs**

General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

UNIT-V **12Hrs**

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I& II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

ANURAG GROUP OF INSTITUTIONS
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M.Pharmacy I year I Sem. **T/P C**

-/12 6

(MPA 105P) PHARMACEUTICAL ANALYSIS PRACTICAL I

1. Analysis of Pharmacopoeial compounds and their formulations by UV Visspectrophotometer
2.Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Imupurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

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

4/- 4

(MPA201T) ADVANCED INSTRUMENTAL ANALYSIS

60 Hours

SCOPE

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

OBJECTIVES

After completion of course student is able to know,

1. interpretation of the NMR, Mass and IR spectra of various organic compounds
2. theoretical and practical skills of the hyphenated instruments
3. identification of organic compounds

UNIT-I **12Hrs**

HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

UNIT-II **12Hrs**

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

UNIT-III **12Hrs**

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

UNIT-IV **12Hrs**

Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of

flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

UNIT-V **12Hrs**

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 with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

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. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
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. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

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

4/- 4

(MPA202T) MDDERN BIO-ANALYTICAL TECHNIQUES

60 Hours

SCOPE

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

OBJECTIVES

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

1. Extraction of drugs from biological samples
2. Separation of drugs from biological samples using different techniques
3. Guidelines for BA/BE studies.

UNIT-I **12Hrs**

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

UNIT-II **12Hrs**

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT-III **12Hrs**

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), the effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT-IV **12Hrs**

Cell culture techniques: Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

UNIT- V **12Hrs**

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes. 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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

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

4/- 4

(MPA203T) QUALITY CONTROL AND QUALITY ASSURANCE

60 Hours

SCOPE

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES

At the completion of this subject it is expected that the student shall be able to know

1. the cGMP aspects in a pharmaceutical industry
2. to appreciate the importance of documentation
3. to understand the scope of quality certifications applicable to Pharmaceutical industries
4. to understand the responsibilities of QA & QC departments

UNIT-I **12Hrs**

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

UNIT-II **12Hrs**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

UNIT-III **12Hrs**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

UNIT-IV **12Hrs**

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

UNIT-V **12Hrs**

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

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

4/- 4

(MPA204T) HERBAL AND COSMETIC ANALYSIS

60 Hours

SCOPE

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

OBJECTIVES

At completion of this course student shall be able to understand

1. Determination of herbal remedies and regulations
2. Analysis of natural products and monographs
3. Determination of Herbal drug-drug interaction
4. Principles of performance evaluation of cosmetic products.

UNIT-I **12Hrs**

Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

UNIT-II **12Hrs**

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

UNIT-III **12Hrs**

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT-IV **12Hrs**

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

UNIT-V **12Hrs**

Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.

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

-/12 6

(MPA205P) PHARMACEUTICAL ANALYSIS PRACTICAL II

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories