JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by an Act No.30 of 2008 of A.P. State Legislature)

Kukatpally, Hyderabad – 500 085, Andhra Pradesh (India)

R 15 - ACADEMIC REGULATIONS (CBCS) FOR M. Pharm. (REGULAR) DEGREE PROGRAMMES

Applicable for the students of M. Pharm. (Regular) programme from the Academic Year ***2015-16*** 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. However, he is permitted to write the examinations for two more years after four academic years of course work, 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. Hospital and Clinical Pharmacy
3. Pharmaceutics
4. Pharmaceutical Chemistry
5. Pharmaceutical Technology
6. Pharmacognosy
7. Pharmacology
8. Pharmaceutical Analysis and Quality Assurance

9. Pharmaceutical Management & Regulatory Affaires
10. Quality Assurance
11. Quality Assurance & Pharma Regulatory Affairs,

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 classwork 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 ATTENDANCE

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 his attendance is less than 75%.

5.2 Condonation of shortage of attendance in each subject up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee.

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 fee shall be payable towards condonation of shortage of attendance.

5.6 A Candidate shall put in a minimum required attendance at least three (3) theory subjects in I Year I semester for promoting to I Year II 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 into 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 practicals, 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. 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 For conducting laboratory end examinations of all PG Programmes, one internal examiner and one external examiner are to be appointed by the Principal of the College and the same to be informed to the Director of Evaluation in two weeks before for commencement of the lab end examinations. The external examiner should be selected from outside the College concerned but within the cluster. No

external examiner should be appointed from any other College in the same cluster/any other cluster which is run by the same Management.

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 50 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. Tech. 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 Director of Evaluation. For this, the Principal of the College shall submit a panel of 3 examiners. 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*
80% and above (≥ 80% , ≤ 100%)	O (Outstanding)	10
Below 80% but not less than 70% (≥ 70% , < 80%)	A^+ (Excellent)	9
Below 70% but not less than 60% (≥ 60% , < 70%)	A (Very Good)	8
Below 60% but not less than 55% (≥ 55% , < 60%)	B^+ (Good)	7
Below 55% but not less than 50% (≥ 50% , < 55%)	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 ñ 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 = { $\sum_{i=1}^{N} C_i G_i$ } / { $\sum_{i=1}^{N} C_i$ } .... 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_i is the no. of Credits allotted to the i^{th} Subject, and G_i 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 = { $\sum_{j=1}^{M} C_j G_j$ } / { $\sum_{j=1}^{M} C_j$ } ... for all S Semesters registered (ie., upto and inclusive of S Semesters, S ñ 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 1^{st} 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_j is the no. of Credits allotted to the j^{th} Subject, and G_j represents the Grade Points (GP) corresponding to the Letter Grade awarded for that j^{th} 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 After approval from the PRC, the soft copy of the thesis should be submitted to the University for ANTI-PLAGIARISM for the quality check and the plagiarism report should be included in the final thesis. If the copied information is less than 24%, then only thesis will be accepted for submission.

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

8.9 For Project work Review I in II Year I Sem. there is an internal marks of 50, the evaluation should be done by the PRC for 25 marks and Supervisor will evaluate for 25 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 during the supplementary examination.

8.10 For Project work Review II in II Year II Sem. there is an internal marks of 50, the evaluation should be done by the PRC for 25 marks and Supervisor will evaluate for 25 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 during the supplementary examination.

8.11 For Project Evaluation (Viva Voce) in II Year II Sem. there is an external marks of 150 and the same evaluated by the External examiner appointed by the University. The candidate has to secure minimum of 50% marks in Project Evaluation (Viva-Voce) examination.

8.12 If he fails to fulfill as specified in 8.11, 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.

8.13 The thesis shall be adjudicated by one examiner selected by the University. For this, the Principal of the College shall submit a panel of 3 examiners, eminent in that field, with the help of the guide concerned and Head of the Department.

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

8.15 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.

8.16 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 **88** Credits (with CGPA $\geq$ 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	$6.75 \leq$ CGPA < 7.75
Second Class	$6.00 \leq$ 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 University 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 R15 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 Vice-Chancellor is final.

12.6 The University 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 University.

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 candidate 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 University.
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 practicals 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 University 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 performance in that subject and all the other subjects the candidate 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 University 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 of his 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, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject 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 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 candidate 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 University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate 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 the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate 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. 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 the performance in that subject and all other subjects the candidate 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 that 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 University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
   - (i) A show cause notice shall be issued to the college.
   - (ii) Impose a suitable fine on the college.
   - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE / QA
COURSE STRUCTURE AND SYLLABUS

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Separation Techniques	25	75	4	--	4
Core Course II	Advanced Pharmaceutical Analysis – I	25	75	4	--	4
Core Course III	Quality Control of Bulk Drugs and Formulations	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Technique 2. Intellectual Property Rights and Regulatory Affairs	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology, Pharmacoeconomics and Pharmacovigilance 2. Drug Regulatory Affairs (National And International) 3. Herbal Cosmetics Technology 4. Pharmaceutical Management – I 5. Advanced Physical Pharmaceutics	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	4	--	4
Laboratory II	Advanced Pharmaceutical Analysis-I Lab	25	75	--	4	2
Seminar I	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Advanced Pharmaceutical Analysis – II	25	75	4	--	4
Core Course V	Spectral Analysis	25	75	4	--	4
Core Course VI	Quality Assurance	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Pharmaceutical Product development and Management 5. Pharmaceutical Management-II	25	75	4	--	4
Laboratory III	Advanced Pharmaceutical Analysis – II Lab	25	75	4	--	4
Laboratory IV	Spectral Analysis Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	P	C
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review I	50	--	--	24	12
Total Credits			--	24	**16**

II Year - II Semester

Course Title	Int. marks	Ext. marks	L	P	C
Project work Review II	50	--	--	8	4
Project Evaluation (Viva-Voce)	--	150	--	16	12
Total Credits			**--**	**24**	**16**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

SEPARATION TECHNIQUES

Objective: The topics of various chromatographic methods from simple to advanced techniques are discussed in detail. The principles, instrumentation and method development parameters are discussed.

UNIT: I

a. **Column Chromatography and Short column chromatography**: Column packing, sample loading, column development, detection.
b. **Flash chromatography and Vacuum liquid chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.

UNIT-II

Sample Preparation - Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

UNIT: III

a. **HPLC:** Principles, basic parameters Retention factor, Capacity factor, Selectivity factor, plate number, plate height, resolution, peak shapes, band broadening, van Deemter equation and curve. Column selection and optimization, column problems, solvents, trouble shooting, sample preparation.
b. **Method Development and validation:** Introduction, Forced Degradation Studies -Experimental Approach to Forced Degradation Studies. Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization and validation.

UNIT-IV

a. **Gas Chromatography:** Principles, split-splitless injector, head space sampling, columns for GC, detectors, quantification, derivatization techniques.
b. **Hyphenated techniques:** Introduction to GC-MS and LC-MS techniques and their applications.

UNIT-V

a. Electrophoresis: Capillary electrophoresis: Basic principle (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.
b. **Counter current chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.

Outcome: The students will learn the every aspect of separation methods, also sample preparation and method validation process. They will come out with full knowledge of various methods including the instrumentation, handling and uses.

REFERENCES:

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
13) Methods in Biotechnology, Natural Product Isolation by Richard Canell
14) Various Reviews and Research Papers

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS – I

Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

UNIT I

Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods

UNIT II

A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl

UNIT III

Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

a. MBTH (3-methyl-2-benzothiazolone hydrazone)
b. F.C. Reagent (Folin-Ciocalteu)
c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
d. 2, 3, 5 - *tri*Phenyltetrazolium salt
e. 2,6 *di* -ChloroquinoneChlorimide
f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)

UNIT-IV

a. **Atomic Absorption Spectrometry (AAS):** Principle, instrumentation, sample automization techniques, interferences. Elemental analysis such as determination of Sodium, Potassium, Calcium, Chlorine, Bromine and Iodine.
b. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.

UNIT-V

a. **Dissolution Method Development:** Physical and Chemical Properties of API, Dissolution Apparatus Selection, Dissolution Medium Selection, Key Operating Parameters, Method Optimization, Validation, Automated Systems.
b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

Outcome: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

TEXT BOOKS

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners

REFERENCES

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

QUALITY CONTROL OF BULK DRUGS & FORMULATIONS

Objective: The quality control aspects like in process quality control tests, impurity profiles, quality control of nutraceuticals and excipients.

UNIT I

Impurity Profiling of Pharmaceuticals: Sources of impurities, their effect on drug stability and therapeutic actions. Determination of impurities in bulk drugs and Formulations: Isolation, characterization and analytical methods.

UNIT II

In process quality control tests carried on the following dosage forms

A. Tablets B. Capsules C. Parenterals D. Liquid Orals

UNIT III

Quality Control of Excipients: Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest: disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT IV

Quality Control of Nutraceuticals: Vitamins (A, B_1, B_2, B_{12}, C, D, E and K), micro nutrients and health supplements including free radical scavengers.

UNIT V

Quality Control of Food Constituents: Carbohydrates, proteins and fats with emphasis in the determination of moisture, ash, nitrogen and physical constituents. Analytical methods for milk

TEXT BOOKS

1)Pharmaceutical Chemistry by Beckett and Stanlake
2)Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
3)Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
4)Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
5)Ahuja S, Alsante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Academic press, California, 2003

Outcome: The quality aspects bulk drugs, excipients nutraceuticals etc. and their control is clearly understood. The precautions to be taken during the process of manufacturing the formulations are also learned.

REFERENCE BOOKS

1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2) David Pearson. The Chemical Analysis of Foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.
3) Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
4) Indian Pharmacopoeia 2012

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Core Elective-I)

Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

REFERENCES :

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors

4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia 2007
13) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14) Introduction to instrumental analysis by Robert. D. Braun

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS
(Core Elective-I)

Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Intellectual Property Rights:

UNIT I
Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT II
a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT III

a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
b. Background, Salient Features and Impact of International Treaties / Conventions like
i. Paris Convention, Berne convention
ii. World Trade Organization (WTO)
iii. World Intellectual Property Organization (WIPO)
iv. Trade Related Aspects of Intellectual Property Rights (TRIPS)
v. Patent Co-operation Treaty (PCT), Mandrid Protocol

Regulatory Affairs

Unit IV
a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

Unit V
a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10

Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

RECOMMENDED BOOKS:
1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi

2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India
3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE
(Open Elective I)

Objective: This course is designed to impart knowledge and skills in epidemiology, economics and vigilance of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

Unit-I
Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.
Measurement of outcomes in pharmacoepidemiology Outcome measures and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Unit-II
Concept of risk in pharmacoepidemiology, Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio
Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross–sectional studies, cohort studies, case control studies, case–cohort studies, meta–analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Unit-III
Sources of data for pharmacoepidemiological studies Adhoc data sources and automated data systems.
Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

Unit-IV
Pharmacoeconomics: Definition, history, need of pharmacoeconomic evaluations Role in formulary management decisions.
Pharmacoeconomic evaluation Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility
Applications of Pharmacoeconomics, Softwares used and case studies

Unit-V
a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, Mechanism, predisposing factors, causualilty assessment (different scales used)
c. Reporting, evaluation, monitoring and management of ADRs
d. Role of pharmacist in management of ADRs.

Outcome: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmocovigilance.

REFERENCES:

1. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
2. Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974 Edition. McGraw Hill.
3. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004
4. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hil

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)
(Open Elective I)

Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

UNIT I
A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

UNIT II
The Drugs and Cosmetics Act, 1940 and Rules there under. Recent amendments to Drugs and Cosmetic Act and other relevant rules.
Drugs (Price Control) Order in force. Loan license (contract manufacture). Certification and licensing procedures.

UNIT III
A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV
Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V
Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

Outcome:
1. Students will come to know the different competent regulatory authorities globally.
2. Students be aware of technical aspects pertaining to the marketing authoritization application(MAA)

The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals

TEXT AND REFERENCE BOOKS
1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (PAQA/QA)

HERBAL COSMETICS TECHNOLOGY
(Open Elective I)

Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation

UNIT I

a) Introduction, historical background and present status of Herbal cosmetics
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Moulding, Packing. Raw materials used in preparation of herbal cosmetics
c) Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery
d) Quality, safety and efficacy of Herbal cosmetics

UNIT II

Skin care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT III

Hair care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like hair dyes, creams, Lotions, Jels, oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as *Acacia concinna* pods, Aloe Vera, Almond oil, Neem, *Citrus aurantium*peels*,* Henna, Turmeric, Liquorice, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

UNIT V

a) General Principles of Quality control and standardization of cosmetics-Raw material control, Packaging material control, finished product control, Shelf testing.
b) Natural colorants : Biological Source, coloring principles, chemical nature and usage of the following Annato, Cochineal, Caramel, Henna, Indigo, Madder, Saffron , Turmeric
c) Flavors and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Vanilla, Palmarosa, geranium oil

Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P.Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA&QA)

PHARMACEUTICAL MANAGEMENT-I
(Open Elective I)

Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

Outcome: These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.

Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.

Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry.

TEXT BOOKS AND REFERENCE BOOKS

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.
11. Personnel Management and Industrial Relations by P. C. Tripathi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M. Pharm (PAQA&QA)

ADVANCED PHYSICAL PHARMACEUTICS
(Optional Elective –I)

Objective: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

UNIT I
Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive ,Hydrodynamically balanced and Transdermal Systems.

UNIT II
Physics of tablet compression: Basic principles of interactions,compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III
Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV
Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, drug release from suspension and emulsion formulations. Accelerated stability evaluation of physical stability. Microemulsions & multiple emulsions, types of viscometer-principle & working.
Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

UNIT V
Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

Outcome: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to *invitro/invivo* correlations.

TEXT BOOKS
1. Physical Pharmacy , 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman Vol.4
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II
4. Cartenson “Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

REFERENCE BOOKS
1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I SemM.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS - I LAB

List of experiments

1. Determination of official compounds by Non-aqueous titrations
2. Determination of drugs containing di and trivalent metal ions by complexometric titrations
3. Determination of sulfa drugs by diazotization
4. Determination of Vitamin C by redox titration
5. Quantitative determination of hydroxy, carboxyl. amino and carbonyl groups present in drugs
6. Quantitative determination of suitable drugs using the reagents mentioned in Unit III
7. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides and steroids