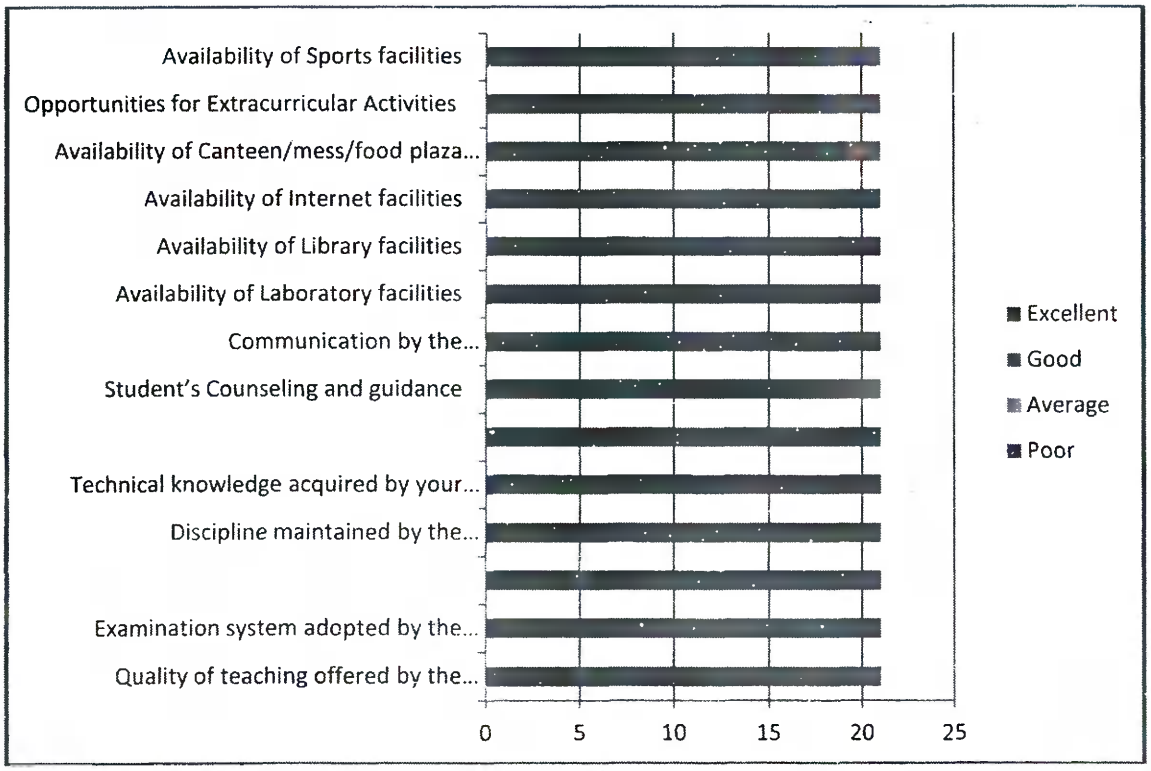
Ramanbhai Patel College of Pharmacy-CHARUSAT
A. Y. 2015-16
PARENTS' FEEDBACK ANALYSIS

✓ **Tick appropriate cell. Scale: 1-Excellent; 2-Good; 3-Average; 4-Poor – 12BPH (21)**

S. No	Criterion	1(a)	2(b)	3(c)	4(d)
1	Quality of teaching offered by the Department/Institute	12	9	0	0
2	Examination system adopted by the Department/Institute	10	11	0	0
3	Depth, Extent of coverage and Relevance of a Syllabus	9	12	0	0
4	Discipline maintained by the Department/Institute	8	13	0	0
5	Technical knowledge acquired by your ward after the admission to the Department/Institute	11	10	0	0
6	Communication and Interpersonal skills acquired by your ward	10	11	0	0
7	Student's Counseling and guidance	14	5	2	0
8	Communication by the Institute/Department	10	11	0	0
9	Availability of Laboratory facilities	12	9	0	0
10	Availability of Library facilities	9	12	0	0
11	Availability of Internet facilities	9	12	0	0
12	Availability of Canteen/mess/food plaza facilities	10	9	2	0
13	Opportunities for Extracurricular Activities	11	7	3	0
14	Availability of Sports facilities	9	9	3	0



Average= (d*1) + (c*2) + (b*3) + (a*4) / total no of responses= 3.46
% response = (Average*100/4)= 86.39%

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A. Reason for selection of this institute for your ward?

- Reputation of the college.
- Infrastructure,wel equipped laboratories
- Good faculty members.
- Inspired by my relatives who have studied here.

B. Your suggestions for improvement in syllabus

- Decrease coaching hours.
- Syllabus should be updated as per the industry demand so it can be useful for the job
- Sophisticated instruments' training should be given to the students.
- Increasing working hours.

C. Your suggestions for further improvement in Department/Institute

- The rules of the university should be same for all the institutes.
- Analytical Training of the students for some equipments' handling should be arranged.
- Industrial visits should be arranged on time.
- A.C. Classroom.
- Students should not be detained in external exams.

D. Your view/opinion about the academic program of your ward

- Nice improvement in my ward's career.
- Other short time training should also be included.

E. Which area in your opinion, your ward can improve further?

- Study
- Extra curricular participation.

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Ramanbhai Patel College of Pharmacy, CHARUSAT
Feedback Analysis for Outgoing students
Academic Year 2015-16

Feedback from outgoing students

Programme: B. Pharm **Date:27/05/2016**
No of responses: 55
Scale-5: Strongly Agree, 4: Agree 3: Moderate 2: Disagree 1: Strongly Disagree

No.	Aspect	5	4	3	2	1	Average	% Response
1	Program's curriculum was broad enough to meet needs and prepare me for my career of choice.	15	25	10	5		4	78
2	The curriculum actively facilitated the learning of various aspects of Pharmacy	23	18	9	3	2	4	81
3	The learning was supplemented by co curricular activities such as coursework outside the department, internships and workshops, Conference, Symposia etc.	17	24	8	6		4	79
4	The curriculum prepared students for academic careers.	12	26	9	6	2	4	75
5	The curriculum prepared students for careers outside academia.	18	20	10	7		4	78
6	The program curriculum could enhance my thinking ability for solving problems and making decision in my day to day life.	20	25	8	2		4	83
7	The studies in B.Pharm at RPCP made me technically sound for solving technical problems in my professional work.	11	31	9	3	1	4	77
8	The activities included in curriculum as well as my participation in extracurricular activities at RPCP helped me in developing the of skill taking strategic decisions.	6	35	6	6	2	4	73
9	Time spent in laboratory and for projects was helpful to me in learning the aspects of timely submission of the work.	27	14	10	1	3	4	82
10	I am now aware about my professional and social responsibilities as a Pharmacist and that came from my studies at RPCP.	31	16	2	6		4	86
11	"Honesty at work and Honesty in life" this principle was consolidated during the time I spent at RPCP.	8	34	8	5		4	76
12	During my studies the issues related to ethics in the profession was discussed and had a great impact on my professional behavior.	13	28	6	4	4	4	75
13	I own information about State Pharmacy Council and Pharmacists Registration Procedure in India.	20	33	1	1		4	86

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14	As a student of RPCP , I believe that, we were trained in interpersonal skills such as public speaking, working in teams etc.	11	32	6	2	4	4	76
15	Do you participate any of the event/s, through institute facilitation, aimed to aware local population about health issues and awareness camp, blood donation camp, organ donation campaign, relies etc.During your tenure of studies at RPCP?	17	30	5	3		4	82
16	Do you believe that Pharmacy Week/ Pharmacist day celebration at RPCP correlated with theme proposed for respective years?	25	16	10	4		4	83
17	The program adequately prepared me for a career in my field .	24	22	5	2	2	4	83
18	Curriculum of B. Pharm Program encouraged me to learn new things and helped me in my continuous development of my profession abilities.	31	14	4	2	3	4	84
19	Rate the ability of curriculum to impart the knowledge and skills which you think, that you may take up for learning voluntarily throughout your professional life.	10	38	5	1	1	4	80
20	Curriculum set, made you capable of analyzing your strength and weakness and motivated you to use resources effectively together the knowledge/skills expected from you.	13	34	5	3		4	81
21	Curriculum made you aware about sustainable growth and conservation of natural resources.	23	24	5	3		4	84
Average							4	80

Average= (a*5) + (b*4) + (c*3) + (d*2) + (e*1)/ total no of responses
% response = (Average*100/5)

Any other comments/ suggestions: NIL

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Ramanbhai Patel College of Pharmacy, CHARUSAT

Feedback Analysis- Teachers

Academic Year 2015-16

For Curriculum

Number of Reviewers from Industry: 0

Number of Reviewers from Academia: 20

Scale- 5: Excellent, 4: Very good, 3: Good, 2: Satisfactory 1: Needs Improvement

Sr.No.	Criterion	5	4	3	2	1	Average	% Response
1	Content of Syllabus	10	7	3	0	0	4.35	87.00
2	Relevance of Syllabus to Industry/Research Requirements	11	4	5	0	0	4.30	86.00
3	Incorporation of Advanced Topics	13	3	1	0	0	4.00	80.00
4	Component Weightage	15	2	3	0	0	4.60	92.00
5	Setting Prerequisite	10	7	3	0	0	4.35	87.00
6	Electives in Curriculum	13	5	2	0	0	4.55	91.00
7	Industrial training in Curriculum	12	6	2	0	0	4.50	90.00
8	Project Component	10	7	3	0	0	4.35	87.00
9	Pedagogy Proposed	9	6	6	0	0	4.35	87.00
10	Linkage between Theory to Practical	13	5	2	0	0	4.55	91.00
Average							4.39	87.80

Average= (a*5) + (b*4) + (c*3) + (d*2) + (e*1)/ total no of responses
% response = (Average*100/5)

Course specific comments:

Additional suggestions and remarks, if any:
The syllabus should include the industry relevant topics or courses.

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Ramanbhai Patel College of Pharmacy, CHARUSAT
Feedback Analysis for Alumni Meeting
Academic Year **2015-16**

Date and Time of the meeting: 12/04/2016

Venue for the meeting:
Ahmedabad Management Association, Ahmedabad

Agenda for the meeting:

To discuss the institutional yearly progress.
To have suggestions for recent job needs and scope for the improvement in teaching and learning processes at the nstitute.

No of responses received: 63

Rate your Curriculum: Scale- 5: Challenging, 4: Adequate, 3: Inadequate, 2: Dull 1: Irrelevant

Criteria	5	4	3	2	1	Avg	% Avg
The curriculum was	19	41	3	-	-	4.25	85.08
Your background for benefiting from the program was	21	42	-	-	-	4.33	86.67
When you meet students who have taken a similar Program at other universities do you feel that your Program is?	38	21	4	-	-	4.54	90.79
Learning value (in terms of skills, concepts, knowledge, analytical abilities, or broadening perspectives)	19	32	10	1	1	4.06	81.27
Applicability/relevance to real life situations	12	31	16	3	1	3.79	75.87
Extent and depth of content	15	29	12	6	1	3.81	76.19
Extent of coverage	12	29	18	3	1	3.76	75.24
Relevance/learning value of project/ training	16	29	15	3	-	3.92	78.41
Average						4.06	81.19

Average= (a*5) + (b*4) + (c*3) + (d*2) + (e*1)/ total no of responses
% response = (Average*100/5)

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Any other suggestion for improvement:

- Internal exam should be of 40 marks instead of 80 marks

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- Tell students 6 month training in hospital and 6 month training in compny complsary so as a pharmacist in medical store they are easily know all the medicine and uses.
- Narrow downing gap between industry and academy.
- In course cover some topic like usfda, mhra, tga in details which are more important in pharma industry.
- The connection that faculty makes with student is amazing and that is what makes student to take interest in particular subject. That connection should never be compromised.
- It has been a great experience of being at RPCP, Personally I have visited many colleges and met students from different universities. Our college is better at many terms

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Ramanbhai Patel College of Pharmacy
Charotar University of Science and Technology
CHARUSAT Campus, Changa

Curriculum feedback analysis and action taken report
Academic Year: 2015-2016

Stake holder	No of feedback received	% feedback analysis	Major concerns	Action taken
Students	55	80	The curriculum should prepare the students for all sorts of career options, academic or outside academia.	Choice based credit system was incorporated to make the students ready for the career options of their choices. (Annexure-I: Minutes of 17th joint meeting of Board of Studies and Faculty Board)
Alumni	63	81.19	The curriculum should show relevance to the real life situation and it should include training/ project component.	The curriculum offered various elective courses at institute as well as university level, both with a small practical/project component. (Annexure-II: Scheme of Teaching and Evaluation)
Employers	4	85.05	No major concern was shown by the employers for any of the attributes.	The institute understands the scope of improvement and always strive to improve the same.
Teachers	5	87.80	No major concern was shown by the teachers for any of the attributes.	The institute understands the scope of improvement and always strive to improve the same.
Parents	28	83.6	No major concern was shown by the teachers for any of the attributes.	The institute understands the scope of improvement and always strive to improve the same.

Ramanbhai Patel College of Pharmacy CHARUSAT CHANGA

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17

CBCS Implementation [B.Pharm + M.Pharm
+ University Electives — PH825 Com. Ph
— PH826 JPR

CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY
(CHARUSAT)
JOINT MEETING OF BOARD OF STUDIES IN PHARMACY &
FACULTY BOARD OF PHARMACY

Date: 24/08/2016 Time: 10:30 a.m.

Place: RPCP Conference room

MINUTES

Members Present (Enclosure I)

1	Dr.Anuradha Gajjar	Chairperson for the joint meeting of Board of Studies in Pharmacy & Faculty Board of Pharmacy (Dean, Faculty of Pharmacy)
2	Dr. Manan Raval	Member - Faculty Board of Pharmacy and Chairperson –Board of Studies in Pharmacy
3	Dr. Gaurang B. Shah	Member -Board of Studies in Pharmacy
4	Dr. M.T. Chabaria	Member -Board of Studies in Pharmacy
5	Dr. Samir Patel	Member -Board of Studies in Pharmacy
6	Ms. Payal Shah	Member -Board of Studies in Pharmacy
7	Ms. Jalpa Suthar	Member -Board of Studies in Pharmacy
8	Dr. Vijay Parmar	Special Invitee
9	Dr. Gayatri Patel	Special Invitee

Following members could not attend the meeting due to their other preoccupations:

10	Dr. R.S.R. Murthy	Member - Faculty Board of Pharmacy
11	Dr. S.B. Roy	Member - Faculty Board of Pharmacy
12	Mr. Bhavesh Patel	Member -Board of Studies in Pharmacy & Faculty Board of Pharmacy
13	Prof. A.N. Misra	Member -Board of Studies in Pharmacy
14	Dr. Dushyant R. Patel	Member -Board of Studies in Pharmacy
15	Mr. V.S. Patel	Member -Board of Studies in Pharmacy
16	Dr. N.R. Sheth	Member -Board of Studies in Pharmacy & Faculty Board of Pharmacy

Item No. 17.1 *To approve the minutes of Joint Meeting of Board of Studies and Faculty Board of Pharmacy, circulated through e mail, dated 12/04/2016*

Proceedings
Minutes of last submission to the board members vide e mail, and the minutes of that circulation, were read by Dr. Manan Raval in meeting. The Chairperson invited suggestions from the members present. There were no suggestions.

Resolution:
Minutes of the meeting convened through circulation were confirmed.

Item No.17.2 *To review and recommend syllabus of courses to be offered by Faculty of Pharmacy as University Level Electives to PG students of CHARUSAT*

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Proceedings
The Chairperson briefed the members that, different faculties of CHARUSAT have proposed University Level Electives for PG students, were recommended by

their respective boards. The same were reviewed with syllabi collectively (across the university) and Faculty of Pharmacy was requested to submit new University Level Electives. The following two University Level Electives, to be offered by Faculty of Pharmacy to PG students are proposed.

Semester	Course Code	Title of Course	Syllabus Drafted By
1st	PH825	Community Pharmacy Ownership	Dr. Jalpa Suthar, Asst. Prof, Dept of Pharmacology and Clinical Pharmacy, RPCP
2nd	PH826	Intellectual Property Rights	Dr. Samir Patel, Assoc. Prof, Dept of Chemistry and Pharm. Analysis. RPCP

Following suggestions were received from the members of the Boards:

Sr. No.	Course (No. ,	Suggestion from	Suggestion/Comment
1	PH825, Community Pharmacy Ownership	Dr. G.B. Shah	Incorporation of more components of pharmacy practice regulation
2		Dr. M.T. Chhabria	This course may not attract engineering students although few students of Nursing & Physiotherapy may be interested.
3	PH826, Intellectual Property Rights	Dr. Anuradha Gajjar	Chapter on Case Study may be taken up as a part in pedagogy and so the syllabus may contain three topics.

Resolution:

The Board recommended the scheme of teaching, scheme of evaluation and syllabus of elective courses to be offered in 1st and 2nd Semester of Post Graduate programmes under different faculties of CHARUSAT as per Enclosure II.

Item. No.17.3. *To review and recommend altered scheme of teaching of M.Pharm programme*

Proceedings

Dr. Anuradha Gajjar explained to the members about total credits of PG programme offered by Faculty of Pharmacy was higher when compared to those with PG programmes offered by other faculties in CHARUSAT. There was an attempt to reduce the total credits of the programme with minimum alteration in the existing structure of approved scheme of teaching and evaluation. This was done by reduction in the credits of dissertation components.

The members were also briefed about the need of changing the course code of existing courses, in newly implemented CBCS, to attain similarity with courses of other faculties in CHARUSAT.

The members suggested the need of adopting the uniform and documented methodology for continuous assessment of dissertation work by internal evaluator. The Dean- Faculty of Pharmacy accepted the suggestion along with other suggestions of members, including exploring the possibility of issuing the laboratory note to the students working for dissertation and evaluation of students performance and learning

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by the internal evaluator on the basis of pre set learning attributes.

Resolution:
It was resolved to reduce the credits allocated to dissertation courses in semester 3 and in semester 4 of all postgraduate programmes offered by Faculty of Pharmacy. The course common to all postgraduate programmes PH 824.01 Scientific Communication was discontinued from existing scheme of teaching and evaluation for all post graduate programmes.

The course codes of all the courses have been changed.
Altered scheme of teaching and evaluation for different post graduate programmes to be offered by Faculty of Pharmacy is attached as Enclosure III.

Item. No.17.4 *To review and recommend altered scheme of teaching of B.Pharm programme*

Proceedings
The Chair person briefed the members about guidelines of UGC for implementation of CBCS. After considering the guideline, current credit allocation to the practical component had to be reduced to half of the existing, which might create the total credits of semester in decimal digit. To make sum of the digits of credit an integer for each semester of B.Pharm programme, few practical courses were allocated 2 credits and few were allocated 1 credit. Credits for tutorials in courses offered by Department of Mathematics were proposed to be discontinued.

Resolution:
The Members of the Boards were of the opinion that, the reduction in the credits of practical components as compared to theory courses, might affect the importance of practicals. The altered scheme of teaching of B.Pharm programme was recommended to Academic Council (Enclosure IV). However, the members have recommended that in the next major revision in B.Pharm structure, care should be taken to have due weightage/ number of credits for practical courses.

Item. No.17. 5 To discuss the new pedagogy adopted at RPCP

Proceeding:
Dr. Manan Raval briefed the members about the new pedagogy adopted at RPCP by faculty members, as in Enclosure V.

Resolution:
The Members of the Boards appreciated the enthusiasm of the faculty members and suggested to evaluate the effectiveness of these new methods in learning enhancement through appropriate approaches.

Item. No.17. 6 To review and discuss the result analysis of B.Pharm programme

Proceeding and Resolution:
Dr. Anuradha Gajjar introduced the members to new format of result analysis (Enclosure VI). She stressed up on the need of the detailed analysis as well as need of evaluating the data comparatively each time with past data.
The members noted the result analysis and accepted this new approach of presenting and comparing the result analysis to ascertain the improvement in result of university examinations.

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Item. No.17. 7 **To review and discuss – Quality of Question Papers of University Examination**

Proceeding and Resolution:

1. Question Papers of all courses of 1st to 8th Semester of B.Pharm Programme of Academic Year 2014-15 and Academic Year 2015-2016 to be assessed for quality by Subject Expert. A questioner was prepared for the purpose.
2. Dr. M.T. Chhabria assessed question papers of Pharmaceutical Chemistry and Analysis Department, Dr.B.G.Shah evaluated question papers of Pharmacology and Clinical Pharmacy Department.
3. It was proposed that Dr.N.R.Sheth would be requested to evaluate question papers of Pharmacognosy Department.

As external subject experts from the discipline of Pharmaceutics were not present in the meeting, members of the board authorized the Dean- Faculty of Pharmacy to get them assessed by identifying appropriate experts. The Board resolved to submit comprehensive report to the university.

Item. No.17. 8 To approve Panel of Examiners for different programmes offered by Faculty of Pharmacy

Resolution:

It was resolved to approve the proposed Panel of examiners for different courses of B. Pharm. programme, M.Pharm. programme (Pharmaceutical Technology, Quality Assurance, Pharmacology, Clinical Pharmacy and Pharmaceutics: (Drugs Regulatory Affairs) and Certificate Programme (Certificate Programme in Cosmetic Technology and Certificate Programme in Packaging Technology). The panel of examiners was submitted to Deputy Registrar – CHARUSAT (Exam) separately.

Item. No.17. 9 To review and recommend Programme Educational Objectives [PEOs] for B.Pharm programme

Proceeding and Resolution:

The members reviewed and recommended the Progrmme Educational Objectives, prepared by the group of the faculty members after considering the Mission Statement of the Institute as well the university as CHARUSAT. They also considered the Graduate Attributes proposed by the NBA, while drafting PEOs. (Enclosure VII). The members reviewed the PEOs and recommended the same.

Item No.17.10

1 Approval of the Synopsis submitted by Research Scholar Mr. Umang Shah
Title of the thesis to be submitted is "Design, Synthesis and Biological Evaluation of Some Heterocycles as Non Steroidal Aromatase Inhibitors"
Research Supervisor: Dr. Samir Patel, Associate Professor – Pharma. Chem. and Analysis, RPCP, CHARUSAT and review of the Panel of Examiners suggested by the Research Supervisor

2 Approval of the Synopsis submitted by Research Scholar Ms. Gopi Shah
Title of the thesis to be submitted is " Development of Hepatotoxicvity Model in Rats and Its Application in Evaluation of Hepatopretctive Activity of Cell Wall Contents of Probiotics"
Research Supervisor: Dr. B.G.Patel, Provost –CHARUSAT and review of the Panel of Examiners suggested by the Research Supervisor

3 Approval of the Synopsis submitted by Research Scholar Ms. Gopi Shah
Title of the thesis to be submitted is "Oral Bioavailability Enhancement of

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3 Approval of the Synopsis submitted by Research Scholar Ms. Gopi Shah
Title of the thesis to be submitted is "Oral Bioavailability Enhancement of Ganciclovir Through Polymeric Nanoparticles Development and Use of Permeation Enhancer"
Research Supervisor: Dr. Balaram Gajra, Former Assoc. Prof –CHARUSAT. Co Supervisors 1. Dr.R.H.Parikh, Former Prof and Principal – RPCP, 2. Dr.Gayatri Patel, Assoc. Prof. Pharmaceutics Department, RPCP and review of the Panel of Examiners suggested by the Research Supervisor

Resolution:

1. ***The Board Members reviewed the synopsis submitted by Mr. Umang Shah, Ms. Gopi Shah and Ms. Rutu Patel and recommended for further processing.***

2. ***The Dean of the Faculty revealed the panel of the examiners suggested by respective Research Supervisor/s for Evaluation of the thesis. The Board Members approved the panel submitted by the Research Supervisor. The panel of examiners would be submitted to Deputy Registrar – CHARUSAT (Exam) separately.***

Item No.17.11 Any other matter with the permission of Chair Person

1 To review revised syllabus of courses offered by Department of Mathematics to B.Pharm programme

Proceeding and Resolution
Department of Mathematics offers three courses to B.Pharm programme. Board of Studies of Department of Mathematics recommended the revision in two courses offered by the department to B.Pharm students in 1st and 2nd Semester B.Pharm (Enclosure VIII).
The board members reviewed the courses and found them competent enough for B.Pharm students

2 To explore the possibility of altering existing course PH 421 Environmental Sciences to be replaced with common course of CL 141Environmental Science

Proceeding and Resolution:
UGC made it compulsory to introduce a course on Environmental Science for undergraduate programme. A course has been introduced for B.Pharm programme. CHARUSAT requested to explore scope of incorporation of general course CL 141 Environmental Science (Enclosure IX) to B.Pharm programme as replacement of this course.

The members reviewed the content of the course and found the structure of the course to be general type instead more inclined towards engineering side. They were of the opinion that the components of Pharmaceutical Sciences and their impact on environment with approaches adopted by Pharmaceutical plants to minimize environmental damage should be present in syllabus for pharmacy students. It was advised not to alter the course PH421 Environmental Sciences.

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The meeting concluded with vote of thanks.

Dr. Manan Raval
Chairperson
Board of Studies in Pharmacy
CHARUSAT

Dr.Anuradha Gajjar
Chairperson
Faculty Board of Pharmacy
CHARUSAT

(Dr. AnuradhaGajjar)
Chairperson- Joint Meeting

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Ramanbhai Patel College of Pharmacy
Charotar University of Science & Technology
Joint Board of Faculty Board of Pharmacy & Board of Studies in Pharmacy

SIGNATURE SHEET

DATE: 24/08/2016

TIME: 10.30 a.m.

Venue: Conference Room, Ramanbhai Patel College of Pharmacy, Changa

Sr. No.	List of Members	Designation	Signature
1.	Dr. Anuradha Gajjar	Chairman for the Faculty Board of Pharmacy Internal Member for the Board of studies in Pharmacy.	
2.	Dr. N. R. Sheth	External Member for the Faculty Board of Pharmacy External Member for the Board of studies in Pharmacy	
3.	Mr. Bhavesh Patel	External Member for the Faculty Board of Pharmacy External Member for the Board of studies in Pharmacy	
4.	Prof. A.N.Misra	External Member for the Board of studies in Pharmacy	
5.	Dr. M.T.Chabaria	External Member for Board of studies in Pharmacy	24.8.16
6.	Dr. Gaurang.B.Shah	External Member for the Board of studies in Pharmacy	
7.	Dr. Dushyant.R.Patel	External Member for the Board of studies in Pharmacy	
8.	Mr. V.S.Patel	External Member for the Board of studies in Pharmacy	
9.	Dr. Manan Raval	Internal Member for the Faculty Board of Pharmacy Chairmen for the Board of studies in Pharmacy	
10.	Dr. Samir Patel	Internal Member for the Board of studies in Pharmacy	
11.	Ms. Payal Shah	Internal Member for the Board of studies in Pharmacy	
12.	~~Ms.~~ Dr. Jalpa Suthar	Internal Member for the Board of studies in Pharmacy	
13.	Dr. Gayatri Patel	Special Invitee- Joint Meeting of Board of studies and Faculty Board of Pharmacy, RPCP	
14.	Dr. Vijay Parmar	Special Invitee- Joint Meeting of Board of studies and Faculty Board of Pharmacy, RPCP	

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Encl

Semester-I

Community Pharmacy Ownership (Elective) (PH825)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objective of the Course

Community pharmacy is concerned with promoting the safe and appropriate use of drugs and common medical devices.

Ownership concept in Community Pharmacy is required to create for the effective delivery of pharmacy services in an regulated environment in which the nature of pharmacy is clearly evolving from the supply of goods (pharmaceuticals under prescription, pharmacist and pharmacy only medicines, and other goods) to the supply of services designed to support the optimal use of medication as part of a wider health care strategy.

Student Learning Outcomes

At the end of the course, the student will be able to understand

- The concept of Community Pharmacy Ownership and its scope
- Students understand the role of the pharmacist in community and development
- Able to learn skill require to set Pharmacy store & its management

Instructional Methods and Pedagogy:

The content of the syllabus would be transmitted through different pedagogy tools, as follows:

Sr.No	Particular	Hours Allotted
1	Class-room interaction	12
2	Group discussion	05
3	Seminar/Assignment	08
4	Case studies	05

Outline of course:

No.	Unit	Minimum No. of Contact Hours Approx.	Weight age %
1	Introduction to Community pharmacy	12	40
2	Community Pharmacy Management	08	27
3	Pharmacy Business Plan	10	33
	Total	30	100%

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CHANGA - 388421, TA. PETLAD, DI. ANAND

Detailed Syllabus

Sr no	Unit Details	No. of Hours
1	**Introduction to Community pharmacy**: Roles & Responsibility, relationship with other health care providers, Prescribed medication order interpretation including OTC medicines, Safe use of medical devices, Introduction to Pharmacy Practice regulations 2015	12
2	**Community Pharmacy Management:** discuss role, process and scope of Community Pharmacy Management, modern technologies, financial, material, staff management and Drug store management, Code of ethics for Pharmacy	08
3	**Pharmacy Business Plan:** Creating a Successful Pharmacy Business Plan, Business Owner Roles, Responsibilities, and Management Styles, The Shops and Establishment Act, 1954, Legal, Financial and Accounting Advice for the Beginning Owner, Marketing of Pharmacy Practice	10

References:

1. Mohd. Aquil, Practice of Hospital, clinical & Community Pharmacy Elsevier
2. Paul Rutter, Community Pharmacy E-Book, Symptoms, Diagnosis and Treatment,3rd Edition
3. A Textbook of Clinical Pharmacy Practice: G. Parthasarathi, Karin Nyfort-Hansen and Milap Nahata, Universities Press.
4. A textbook of Forensic Pharmacy by B. M. Mithal.
5. A textbook of Forensic Pharmacy by N. K. Jain, Vallbh Prakashan.
6. Research articles as per the assignment

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Semester-II

Intellectual Property Rights (Elective) (PH 825)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objectives of the course:

- To acquaint the students with the basic concepts of Intellectual Property Rights;
- To develop expertise in IPR related issues,
- To sensitize the students with the emerging issues in IPR and the rationale for the protection of IPR, and;
- To explore practical aspects repeated to patenting.

Students Learning Outcomes:

- At the end of the course, the student will be able to understand the fundamental concepts of Intellectual Property Rights which further will be helpful in understanding other advanced aspects of Patent and Trademark applications in various scientific research and innovation.
- At the end student would gain experience in filling and drafting procedure of Patent.

Instructional Methods and Pedagogy:

- The content of the syllabus would be transmitted through different pedagogy tools, as follows:

Sr. No	Particular	Hours Allotted
1	Class-room interaction	15
2	Group discussion	05
3	Case studies	05
4	Practice Session for Patent Drafting	05

Outline of the course:

Sr. No.	Title of Unit	No. of Contact Hours.
1	Intellectual Property Concepts	07
2	Practical aspect of patenting	20
3	IPR related treaties	03

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Syllabus Topics:

Sr. No.	Topics	No. of Hours
1	**Intellectual Property Concepts:** • Concept of property, conventional property Vs Intellectual Property • Basic aspect of the 8 different IPR mechanism Viz. Patents, Copyright, trademark, industrial design, layout design of integrated circuits, geographical indicators, plant varieties & trade secrets. • Benefits of IPRs to improve the quality of research work • Strategies for avoiding research duplications, infringements	07
2	**Practical aspect of patenting:-** • **Indian patent act and its recent amendment with respect to following aspect:** Patentable and non-patentable inventions, Essential criteria for filing a patent, Filling a patent in India and abroad, Drafting of patent application • **Patent Filing and Commercialization:** Procedure for patent obtaining in India, National and International Patent Search, Patent Analysis, Patent Drafting and Filling Procedure in India, Patent Specification and Claims, How to right a Claim of Patent, Pre/Post Grant Issues in Patenting, Opposition of Patent Granting, Infringement Analysis, Ground of Defense, Intellectual Property Appellation Board (IPAB), International Filing: PCT System • **Patent and Biodiversity Act** • **Introduction to World Intellectual Property Organization. (WIPO)** • **Commercialization of patent: Need for Commercialization of research and role of IPRs in research Commercialization.** • **Benefit/Disadvantages of patenting to the society** • **Latest Amendment/Emerging Issues in Patenting**	20
3	**IPR related treaties:-** • Patent co-operative treaty • Budapest treaty	03

Recommended Study material

1. Intellectual Property Right basic Concept, by M. M. S. Khatri, Atlantic Publisher and Distributors Pvt. Ltd., New Delhi.
2. Epstein on Intellectual Property: 5th Edition by Michael M. Epstein, Wolters Kulwer India Pvt. Ltd. Gurgaon, India.
3. Intellectual Property Right and Human Development in India by Shabana Talwar, First Edition, Serials Publications, New Delhi, India.
4. IPR Handbook for Pharma Students and Researchers, Parikshit Bansal, Pharma Book Syndicate, Hyderabad, India.
5. Patents, N. R. Subbaram, Pharma Book Syndicate, Hyderabad.
6. Intellectual Property Right by Nikolaus Thumm, Springer-Verlag Publications, Germany.
7. Intellectual Property - Patents, Copyright, TradeMarks and Allied Rights by Cornish, Aplin and Llewelyn, Sweet and Maxwell – Thomson Publishers, New Delhi, India
8. The Enforcement of Intellectual Property Rights: A Case Book by Louis Tc. Harms, WIPO Publishing House, Geneva.
9. Intellectual Property: From Creation to Commercialization - A Practical Guide for Innovators & Researchers by John P., MC Manus, Oak Tree Press, Ireland

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
M. Pharm. (Clinical Pharmacy)
SEMESTER-I
Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC004	Analytical Techniques	Programme Level	Core Course	4	-	--	4
PHCP001	Clinical Pharmacy Practice	Programme Level	Core Course	5	--	--	5
PHCP002	Pharmacotherapeutics -I	Programme Level	Core Course	5	--	--	5
PHCP003	Advance Pharmacokinetics & Clinical Applications	Programme Level	Core Course	4	--	--	4
PHCP004	Clinical Pharmacy Practical-I	Programme Level	Core Course	--	3	--	3
PHCP005	Practical-II (Analytical Techniques)	Programme Level	Core Course	--	3	--	3
HS701 B	Advance Critical Thinking and Logic	University Level	Core Course	2	--	--	2
---	Elective	University level	Elective Course	2	--	--	2
				22	06		28
Total credits: 28							

SEMESTER-II
Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC006	Research Methodology	Programme Level	Core Course	2			2
PHCP006	Pharmacotherapeutics –II	Programme Level	Core Course	5	--	--	5
PHCC005	Clinical Research	Programme Level	Core Course	5	--	--	5
PHCP007	Advance Hospital pharmacy Management	Programme Level	Core Course	4	--	--	4
PHCP008	Clinical Pharmacy Practical-III	Programme Level	Core Course	--	3	--	3
PHCP009	Clinical Pharmacy Practical-IV	Programme Level	Core Course	--	3	--	3
PHCP010	Dissertation- Part-I	Programme Level	Core Course	--	--	3	3
HS702 B	Academic Writing and Communication Skills	University Level	Core Course	--	2	--	2
	Elective	University Level	Elective Course	2	--	--	2
				18	08	03	29
Total credits: 29							

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
M. Pharm. (Clinical Pharmacy)

Semester-3
Scheme of teaching

Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHCP011	Dissertation Part-II	--	--	36	36	--	--	18	18
Total		--	--	36	36	--	--	18	18
Total credits: 18									

Semester-4
Scheme of teaching

Part I: 10 weeks									
Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHCP012	Dissertation Part-III	--	--	36	36	--	--	18	18
Part II: 5 Weeks									
PHCP013	Industrial Training	--	--	--	--	--	--	2	2
Total		--	--	--	--	--	--	20	20
Total Credit :20									

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CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY

M. Pharm. [Pharmaceutics: (Drugs Regulatory Affairs)]

SEMESTER-I

Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC001	Basic Analytical Techniques	Programme Level Core	Core Course	4	--	--	4
PHCC002	Biopharmaceutics & Pharmacokinetics	Programme Level Core	Core Course	4	--	--	4
PHRA001	Pharmaceutical Formulation Development	Programme Level Core	Core Course	5	--	--	5
PHRA002	Drug Regulatory Affairs-I	Programme Level Core	Core Course	5	--	--	5
PHRA003	Drug Regulatory Affairs Practical-I	Programme Level Core	Core Course	--	3	--	3
PHRA004	Drug Regulatory Affairs Practical-II	Programme Level Core	Core Course	--	3	--	3
HS701B	Advance Critical Thinking and Logic	University Level Core	Core Course	2	--	--	2
	Elective	University Level Core	Elective Course	2	--	--	2
				22	06		28
Total credits: 28							

SEMESTER-II

Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC006	Research Methodology	Programme Level Core	Core Course	2			2
PHCC003	GMP,QA & Process Validation	Programme Level Core	Core Course	4	--	--	5
PHRA005	Drug Regulatory Affairs-II	Programme Level Core	Core Course	5	--	--	5
PHRA006	Drug Regulatory Affairs-III	Programme Level Core	Core Course	5	--	--	4
PHRA007	Drug Regulatory Affairs Practical-III	Programme Level Core	Core Course	--	3	--	3
PHRA008	Drug Regulatory Affairs Practical-IV	Programme Level Core	Core Course	--	3	--	3
HS702 B	Academic Writing and Communication Skills	University Level Core	Core Course	--	2	--	2
PHRA009	Dissertation part -I	Programme Level Core	Core Course	--	--	3	3
	Elective	University Level Core	Elective Course	2	--	--	2
				18	8	3	
Total credits: 29							

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
M. Pharm. [Pharmaceutics: (Drugs Regulatory Affairs)]

Semester-3
Scheme of teaching

Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHRA010	Dissertation Part-II	--	--	36	36	--	--	18	18
Total		--	--	36	36	--	--	18	18
Total credits: 18									

Semester-4
Scheme of teaching

Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
Part I: 10 weeks									
PHRA011	Dissertation Part-III	--	--	36	36	--	--	18	18
Part II: 5 Weeks									
PHRA012	Industrial Training	--	--	--	--	--	--	2	2
Total		--	--	--	--	--	--	20	20
Total Credit :20									

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY

M. Pharm. (Quality Assurance)

SEMESTER-I

Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHQA001	Modern Analytical Techniques	Programme Level Core	Core Course	4	--	--	4
PHQA002	QA, GMP, GLP	Programme Level Core	Core Course	5	--	--	5
PHQA003	Pharmaceutical Analysis - I	Programme Level Core	Core Course	5	--	--	5
PHQA004	Clinical research and Drug regulatory affairs	Programme Level Core	Core Course	4	--	--	4
PHQA005	Practical-I (Modern analytical Techniques and Biostatistics)	Programme Level Core	Core Course	---	3	--	3
PHQA006	Practical-II (Pharmacopoeial methods of Analysis)	Programme Level Core	Core Course	---	3	--	3
HS701 B	Advance Critical Thinking and Logic	University Level Core	Core Course	2	--	--	2
Total credits: 28							

SEMESTER-II

Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC006	Research Methodology	Programme Level Core	Core Course	2			2
PHQA007	Pharmaceutical Validation and Documentation	Programme Level Core	Core Course	5	--	---	5
PHQA008	Pharmaceutical Analysis-II	Programme Level Core	Core Course	5	--	---	5
PHQA009	Quality Management of Pharmaceuticals	Programme Level Core	Core Course	4	--	---	4
PHQA010	Practical-III (Advanced Pharmaceutical Analysis)	Programme Level Core	Core Course	--	3	--	3
PHQA011	Practical IV (Pharmaceutical Validation & Documentation)	Programme Level Core	Core Course	--	3	--	3
HS702 B	Academic Writing and Communication Skills	University Level Core	Core Course	--	2	--	2
PHQA012	Dissertation Part I	Programme Level Core	Core Course	---	---	3	3
	Elective	University Level Core	Elective Course	2	--	--	2
				18	8	03	29
Total credits: 29							

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY

M. Pharm. (Quality Assurance)

Semester-3

Scheme of teaching

Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHQA013	Dissertation Part-II	--	--	36	36	--	--	18	18
	Total	--	--	36	36	--	--	18	18
Total credits: 18									

Semester-4

Scheme of teaching

Part I: 10 weeks									
Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHQA014	Dissertation Part-III	--	--	36	36	--	--	18	18
Part II: 5 Weeks									
PHQA015	Industrial Training	--	--	--	--	--	--	2	2
Total		--	--	--	--	--	--	20	20
Total Credit :20									

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
M. Pharm. (Pharmacology and Toxicology)
SEMESTER-I
Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC004	Analytical Techniques	Programme Level Core	Core Course	4	-	--	4
PHCT001	Biological Evaluation of Drugs	Programme Level Core	Core Course	5	--	--	5
PHCT002	Pharmacology –I	Programme Level Core	Core Course	5	--	--	5
PHCT003	Cellular and molecular basis of pharmacology	Programme Level Core	Core Course	4	--	--	4
PHCT004	Pharmacology Practical-I	Programme Level Core	Core Course	--	3	--	3
PHCT005	Practical-II (Analytical Techniques)	Programme Level Core	Core Course	--	3	--	3
HS701 B	Advance Critical Thinking and Logic	University Level Core	Core Course	2	--	--	2
	Elective	University Level Core	Elective Course	2	--	--	2
				22	6		28
Total credits: 28							

SEMESTER-II
Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC006	Research Methodology	Programme Level Core	Core Course	2	---	---	2
PHCC005	Clinical Research	Programme Level Core	Core Course	5	--	--	5
PHCT006	Pharmacology -II	Programme Level Core	Core Course	5	--	--	5
PHCT007	Toxicology	Programme Level Core	Core Course	5	--	--	5
PHCT008	Pharmacology Practical-III	Programme Level Core	Core Course	--	2.5	--	2.5
PHCT009	Pharmacology Practical-IV	Programme Level Core	Core Course	--	2.5	--	2.5
PHCT010	Dissertation- Part-I	University Level Core	Core Course	--	--	3	3
HS702 B	Academic Writing and Communication Skills	University Level Core	Core Course	--	2	--	2
	Elective	University Level Core	Elective Course	2	--	--	2
				19	7	3	29
Total credits: 29							

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
M. Pharm. (Pharmacology and Toxicology)
Semester-3
Scheme of teaching

Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHCT011	Dissertation Part-II	--	--	36	36	--	--	18	18
Total		--	--	36	36	--	--	18	18
Total credits: 18									

Semester-4
Scheme of teaching

Part I: 10 weeks									
Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHCT012	Dissertation Part-III	--	--	36	36	--	--	18	18
Part II: 5 Weeks									
PHCT013	Industrial Training	--	--	--	--	--	--	2	2
Total		--	--	--	--	--	--	20	20
Total Credit :20									

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
M. Pharm. (Pharmaceutical Technology)
SEMESTER-I
Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC001	Basic Analytical Techniques	Programme Level Core	Core Course	4	--	--	4
PHCC002	Biopharmaceutics & Pharmacokinetics	Programme Level Core	Core Course	4	--	--	4
PHPT001	Novel Drug Delivery Systems-I	Programme Level Core	Core Course	5	--	--	5
PHPT002	Pharmaceutical Product Development	Programme Level Core	Core Course	5	--	--	5
PHPT003	**Pharmaceutical Technology** Practical-I	Programme Level Core	Core Course	--	3	--	3
PHPT004	**Pharmaceutical Technology** Practical-II	Programme Level Core	Core Course	--	3	--	3
HS701 B	Advance Critical Thinking and Logic	University Level Core	Core Course	2	--	--	2
	Elective	University Level Core	Elective Course	2	--	--	2
Total credits: 28							

SEMESTER-II
Scheme of Teaching

Course		Classification of Course as Per CBCS		Credits			
Code	Name	General Classification	Specific Classification	Theory	Practical	Project	Total
PHCC006	Research Methodology	Programme Level Core	Core Course	2			2
PHCC003	GMP,QA & Process Validation	Programme Level Core	Core Course	4	--	--	5
PHPT005	Novel Drug Delivery Systems -II	Programme Level Core	Core Course	5	--	--	5
PHPT006	Pharmaceutical Production Management, Technology And Drug Regulatory Affairs	Programme Level Core	Core Course	5	--	--	4
PHPT007	**Pharmaceutical Technology** Practical-III	Programme Level Core	Core Course	--	3	--	3
PHPT008	**Pharmaceutical Technology** Practical-IV	Programme Level Core	Core Course	--	3	--	3
HS702 B	Academic Writing and Communication Skills	Programme Level Core	Core Course	--	2	--	2
PHPT009	Dissertation part -I	Programme Level Core	Core Course	--	--	3	3
	Elective	University Level Core	Elective Course	2	--	--	2
				18	08	3	29
Total credits: 29							

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CHAROTAR UNIVERSITY OF SCIENCE & TECHNOLOGY
M. Pharm. (Pharmaceutical Technology)

Semester-3
Scheme of teaching

Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHPT010	Dissertation Part-II	--	--	36	36	--	--	18	18
Total		--	--	36	36	--	--	18	18
Total credits: 18									

Semester-4
Scheme of teaching

Part I: 10 weeks									
Course		Contact Hours/Week				Credits			
Sr. No.	Name	Theory	Practical	Project	Total	Theory	Practical	Project	Total
PHPT011	Dissertation Part-III	--	--	36	36	--	--	18	18
Part II: 5 Weeks									
PHPT012	Industrial Training	--	--	--	--	--	--	2	2
Total		--	--	--	--	--	--	20	20
Total Credit :20									

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Classification of Courses According to CBCS
BACHELOR OF PHARMACY (B. Pharm.) PROGRAMME
Proposed From Academic year: 2016-2017
SEMESTER-1
SCHEME OF TEACHING

Course Code	Course Name	Classification of Course as Per CBCS		Credit- Existing			Credit – Proposed		
		General Classification	Specific Classification	Theory	Practical	Tutorial	Theory	Practical	Tutorial
PH112	Human Anatomy & Physiology-I	Programme Level Course	Foundation Course	3	---	---	3	---	---
PH122	Elementary Pharmacognosy	Programme Level Course	Foundation Course	3	3	---	3	1.0	---
PH123	Pharmaceutical Chemistry-I	Programme Level Course	Foundation Course	3	3	---	3	2.0	---
PH124	Pharmaceutical Engineering-I	Programme Level Course	Foundation Course	3	3	---	3	1.0	---
PH116	Pharmaceutical Biology-I	Programme Level Course	Foundation Course	2	---	---	2	---	---
MA121	Basic Mathematics	Programme Level Course	Foundation Course	3	---	2	3	---	---
H101B – HS106B	A Course From Liberal Arts	University Level Course	Core Course	---	2	---	---	2	---
			Total	17	11	2	17	6.0	---
				30			23		

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SEMESTER-2

SCHEME OF TEACHING

Course Code	Course Name	Classification of Course as Per CBCS		Credit - Existing			Credit – Proposed		
		General Classification	Specific Classification	Theory	Practical	Tutorial	Theory	Practical	Tutorial
PH125	Human Anatomy & Physiology-II	Programme Level Course	Foundation Course	3	3	---	3	1.0	---
PH126	Pharmacognosy-I	Programme Level Course	Foundation Course	3	3	---	3	2.0	---
PH127	Pharmaceutical Chemistry-II	Programme Level Course	Foundation Course	3	3	---	3	1.0	---
PH128	Pharmaceutical Engineering-II	Programme Level Course	Foundation Course	3	3	---	3	2.0	---
PH121	Pharmaceutical Biology-II	Programme Level Course	Foundation Course	2	---	---	2	---	---
MA122	Advanced Mathematics	Programme Level Course	Core Course	3	---	1	3	---	---
HS121B	English Language & Literature	University Level Course	Core Course	2	---	---	2	---	---
			Total	19	12	1	19	6.0	---
				31			25.0		

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Semester-3

Scheme of Teaching

Course Code	Course Name	Classification of Course as Per CBCS		Credit - Existing		Credit – Proposed	
		General Classification	Specific Classification	Theory	Practical	Theory	Practical
PH215	Pharmacology-I	Programme Level Course	Core Course	3	---	3	---
PH226	Pharmacognosy-II	Programme Level Course	Foundation Course	3	3	3	1.0
PH227	Pharmaceutical Chemistry-III	Programme Level Course	Foundation Course	3	3	3	2.0
PH228	Hospital and Dispensing Pharmacy	Programme Level Course	Core Course	3	3	3	1.0
PH229	Pharmaceutical Engineering-III	Programme Level Course	Foundation Course	3	3	3	2.0
PH230	Pharmaceutical Software	Programme Level Course	Core Course	---	3	---	1.0
HS122B	Values and Ethics	University Level Course	Core Course	2	---	2	---
			Total	17	15	17	7.0
				32		24.0	

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Semester-4

Scheme of Teaching

Course Code	Course Name	Classification of Course as Per CBCS		Credit - Existing		Credit – Proposed	
		General Classification	Specific Classification	Theory	Practical	Theory	Practical
PH231	Pharmacology-II	Programme Level Course	Core Course	3	3	3	2.0
PH232	Phytochemistry I	Programme Level Course	Core Course	3	3	3	2.0
PH233	Pharmaceutical Biochemistry	Programme Level Course	Foundation Course	3	3	3	1.0
PH224	Pharmaceutical Jurisprudence	Programme Level Course	Core Course	3	---	3	---
PH234	Physical Pharmaceutics	Programme Level Course	Foundation Course	3	3	3	2.0
MA221	Biostatistics	Programme Level Course	Core Course	---	3	---	1.0
---	Elective Course	University Level Course	Elective Course	2	---	2	---
			Total	17	15	17	8.0
				32		25	

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CHANGA - 388421, TA. PETLAD, DI. ANAND

Semester-5

Scheme of Teaching

Course Code	Course Name	Classification of Course as Per CBCS		Credit - Existing		Credit – Proposed	
		General Classification	Specific Classification	Theory	Practical	Theory	Practical
PH332	Pharmacology-III	Programme Level Course	Core Course	3	3	3	2.0
PH333	Medicinal Chemistry I	Programme Level Course	Foundation Course	3	3	3	1.0
PH334	Pharmaceutical Analysis-I	Programme Level Course	Core Course	3	3	3	1.0
PH318	Biopharmaceutics and Pharmacokinetics	Programme Level Course	Foundation Course	3	---	3	---
PH335	Pharmaceutical Microbiology and Biotechnology*	Programme Level Course	Foundation / Core Course	3	3	3	1.0
PH320	Pharmaceutical Management	Programme Level Course	Core Course	4	---	4	---
HS124	Professional Communication	University Core Course	Core Course	---	2	---	2
			Total	19	14	19	7
				34		26	

**Microbiology is Foundation course for Biotechnology*

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Semester-6

Scheme of Teaching

Course Code	Course Name	Classification of Course as Per CBCS		Credit - Existing		Credit – Proposed	
		General Classification	Specific Classification	Theory	Practical	Theory	Practical
PH336	Pharmacology-IV	Programme Level Course	Core Course	3	3	3	1.0
PH322	Phytochemistry-II	Programme Level Course	Core Course	3	---	3	---
PH337	Medicinal Chemistry-II	Programme Level Course	Core Course	3	3	3	2.0
PH338	Pharmaceutical Analysis-II	Programme Level Course	Core Course	3	3	3	2.0
PH339	Pharmaceutical Technology-I	Programme Level Course	Core Course	3	3	3	1.0
PH340 PH345	Elective – I	Programme Level Course	Elective Course	2	---	2	---
HS125	Society, Governance and International Studies	University Core Course	Core Course	2		2	
				19 + 12		19	8.0
				31		27	

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Semester-7

Scheme of Teaching

Course Code	Course Name	Classification of Course as Per CBCS		Credit - Existing		Credit – Proposed	
		General Classification	Specific Classification	Theory	Practical	Theory	Practical
PH428	Clinical Pharmacy and Pharmacotherapeutics-I	Programme Level Course	Core Course	3	3	3	1.0
PH429	Traditional Medicine and Herbal Drugs Technology	Programme Level Course	Core Course	3	3	3	2.0
PH430	Pharmaceutical Analysis-III	Programme Level Course	Core Course	3	3	3	2.0
PH418	Medicinal Chemistry-III	Programme Level Course	Core Course	3	---	3	---
PH431	Pharmaceutical Technology-II	Programme Level Course	Core Course	3	3	3	2.0
PH432-PH437	Elective-II	Programme Level Course	Elective Course	2	---	2	---
PH421	Environmental Sciences	Programme Level Course	Core Course	2	---	2	---
			Total	19	12	19	7.0
				31		26	

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Semester-8

Scheme of Teaching

Course Code	Course Name	Classification of Course as Per CBCS		Credit - Existing		Credit – Proposed	
		General Classification	Specific Classification	Theory	Practical	Theory	Practical
PH438	Clinical Pharmacy and Pharmacotherapeutics-II	Programme Level Course	Core Course	3	3	3	2.0
PH439	Medicinal Chemistry-IV	Programme Level Course	Core Course	3	3	3	1.0
PH440	Dosage Form Design	Programme Level Course	Core Course	3	3	3	2.0
PH425	Novel Drug Delivery Systems	Programme Level Course	Core Course	2	---	2	---
PH441-PH446	Elective-III	Programme Level Course	Elective Course	3	3	3	1.0
PH447	Entrepreneurship for pharma professionals	Programme Level Course	Core Course	3	3	3	1.0
			Total	17	15	17	7.0
				32		24.0	

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Summary

Semester	Existing		Proposed	
	Theory	Practical	Theory	Practical
1	17	11+2*	17	6.0
2	19	12+1*	19	6.0
3	17	15	17	7.0
4	17	15	17	8.0
5	19	14	19	7.0
6	19	12	19	8.0 6.0
7	19	12	19	7.0
8	17	15	17	7.0
Total	144	106+3*	144	56 54
Total Credit	**253**		**200** 198	

*Tutorial

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Enclosure V

New Pedagogy Adopted at RPCP

17.5.1 Princ. B.I.Patel Human Research Development Centre conducts sessions for faculty members of constituent institutes. One such session was arranged on application of Information and Communication Technology (ICT) in teaching and learning in higher studies. The faculty members were introduced to Learning Management System (LMS). There are few such online system available, which facilitates the learning of students.

Teachers created group of students on course account. A teacher is always administrator for the account. He/She can conduct tests (different types), seminar allocation and submission, assignment work as well as group activities. These systems facilitate not only learning but provide the facility to teacher to get feedback from students anonymously. Many teachers of RPCP has adopted EDMODO™ , system from current academic year.

17.5.2 RPCP has procured Impartus Lecture Capture System™. This system enables students to review class room recording at any time any where. Nearly, 80 classes for 3rd Semester B.Pharm have been recorded using this system and students have started using those.

17.5.3 One of the major outcomes of courses offered by Pharmacognosy Department in early semesters of B.Pharm programme is to make students capable of identifying the prototype medicinal plant specimens as well as adulteration in those samples, through morphological as well as microscopical evaluation.

At the institute, for long time, it has been realized that such pharmacognostic studies of medicinal plants, involving morphological evaluation of medicinal plant specimens, became monotonous and students found little or no learning components in these studies. It was thought to incorporate field based study component in practical sessions to make the studies interesting as well as challenging.

The students along with the teacher started visiting herbal garden of the institute, where teacher showed them the plant of the studies in natural habitat with similar looking other plants too, up to the extent possible. The students learnt the ways of comparative preliminary identification of such medicinal plants at the location with the help of teacher.

A survey is going to be conducted to access the effectiveness of this newly introduced field based learning.

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Enclosure VI

Based on Percentage - Sem - 2 - 2015-16 (Theory Courses)						
Subject Code		AA	AB		DD	FF
		TH	TH	Total	TH	TH
PH117	HUMAN ANATOMYY & PHYSIOLOGY-II	5.00%	8.00%	13.00%	17.00%	17.00%
PH121	PHARMACEUTICAL BIOLOGY-II	00	9.00%	9.00%	28.00%	10.00%
PH118	PHARMACOGNOSY-I	9.00%	12.00%	21.00%	22.00%	19.00%
PH119	PHARMACEUTICAL CHEMISTRY II	16.00%	8.00%	24.00%	16.00%	26.00%
PH120	PHARMACEUTICAL ENGINEERING -II	7.00%	15.00%	22.00%	14.00%	7.00%
MA141.1	ADVANCED MATHEMETICS	29.00%	8.00%	37.00%	14.00%	28.00%
HS121 B	ENGLISH LANGUAGE AND LITERATURE	6.00%	24.00%	30.00%	1.00%	2.00%

Based on Percentage - Sem - 2 - 2015-16 (Practical Courses)						
Subject Code		AA	AB		DD	FF
		PR	PR	Total	PR	PR
PH117	HUMAN ANATOMYY & PHYSIOLOGY-II	8.00%	19.00%	27.00%	4.00%	7.00%
PH121	PHARMAXCEUTICAL BIOLOGY-II			0.00%		
PH118	PHARMACOGNOSY-I	16.00%	14.00%	30.00%	7.00%	15.00%
PH119	PHARMACEUTICAL CHEMISTRY II	15.00%	14.00%	29.00%	7.00%	6.00%
PH120	PHARMACEUTICAL ENGINEERING -II	2.00%	14.00%	16.00%		9.00%
MA141.1	ADVANCED MATHEMETICS			0.00%		
HS121 B	ENGLISH LANGUAGE AND LITERATURE	34.00%	37.00%	71.00%		10.00%

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Based on Percentage - Sem - 4 - 2015-16 (Theory Courses)						
Subject Code		AA	AB		DD	FF
		TH	TH	Total	TH	TH
HS123 B	CRITICAL THINKING AND LOGIC	30.00%	18.33%	48.33%	1.67%	5.00%
PH221	PHARMACOLOGY -II	6.67%	11.67%	18.34%	28.33%	11.67%
PH222	PHYTOCHEMISTRY-I		8.33%	8.33%	26.67%	26.67%
PH223	PHARMACEUTICAL BIOCHEMISTRY	1.67%	6.67%	8.34%	31.67%	16.67%
PH224	PHARMACUTICAL JURIPRUDENCE	25.00%	23.33%	48.33%		5.00%
PH225	PHYSICAL PHARMACEUTICS	16.67%	18.33%	35.00%	6.67%	6.67%
MA331.1	BIOSTATISTICS			0.00%		

Based on Percentage - Sem - 4 - 2015-16 (Practical Courses)						
Subject Code		AA	AB		DD	FF
		PR	PR	Total	PR	PR
HS123 B	CRITICAL THINKING AND LOGIC			0.00%		
PH221	PHARMACOLOGY -II	21.67%	16.67%	38.34%	3.33%	1.67%
PH222	PHYTOCHEMISTRY-I	3.33%	16.67%	20.00%	10.00%	10.00%
PH223	PHARMACEUTICAL BIOCHEMISTRY	11.67%	8.33%	20.00%	1.67%	6.67%
PH224	PHARMACUTICAL JURIPRUDENCE			0.00%		
PH225	PHYSICAL PHARMACEUTICS	26.67%	28.33%	55.00%	1.67%	3.33%
MA331.1	BIOSTATISTICS	21.67%	11.67%	33.34%	3.33%	10.00%

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Based on Percentage - Sem - 6 - 2015-16 (Theory Courses)						
Subject Code		AA	AB		DD	FF
		TH	TH	Total	TH	TH
PH308	PHARMACOLOGY-III	2.86%	2.86%	5.72%	25.71%	11.43%
PH309	PHARMACOGNOSY & PHYTOCHEMISTRY - IV	8.57%	4.29%	12.86 %	11.43%	5.71%
PH310	MEDICINAL CHEMISTRY-II	4.29%	11.43%	15.72 %	21.43%	10.00%
PH311	PHARMACEUTICAL BIOCHEMISTRY-II	4.29%	8.57%	12.86 %	20.00%	7.14%
PH312	BIOPHARMACEUTICALS	8.57%	20.00%	28.57 %	11.43%	
PH313	BIOPHARMACEUTICS & PHARMACOKINETICS	2.86%	7.14%	10.00 %	24.29%	10.00%
PH314	PHARMACEUTICAL MANAGEMENT-I			0.00%		
MB301	PHARMACEUTICAL SOFTWARES	5.71%	41.43%	47.14 %	2.86%	

Based on Percentage - Sem - 6 - 2015-16 (Practical Courses)						
Subject Code		AA	AB		DD	FF
		PR	PR	Total	PR	PR
PH308	PHARMACOLOGY-III	8.57%	31.43%	40.00%		
PH309	PHARMACOGNOSY & PHYTOCHEMISTRY - IV	27.14%	21.43%	48.57%		
PH310	MEDICINAL CHEMISTRY-II	15.71%	32.86%	48.57%		
PH311	PHARMACEUTICAL BIOCHEMISTRY-II	8.57%	10.00%	18.57%		
PH312	BIOPHARMACEUTICALS	45.71%	28.57%	74.28%		
PH313	BIOPHARMACEUTICS & PHARMACOKINETICS			0.00%		
PH314	PHARMACEUTICAL MANAGEMENT-I	40.00%	30.00%	70.00%		
MB301	PHARMACEUTICAL SOFTWARES			0.00%		

Based on Percentage - Sem - 8 - 2015-16 (Theory Courses)						
Subject Code		AA	AB		DD	FF
		TH	TH	Total	TH	TH
PH408	CLINICAL PHARMACY & PHARMACOTHERPUTICS-II		3.39%	3.39%	23.73%	1.69%
PH409	HERBAL DRUGS TECHNOLOGY-II	3.39%	23.73%	27.12%	3.39%	1.69%
PH410	MEDICINAL CHEMISTRY-IV	1.69%	1.69%	3.38%	27.12%	3.39%
PH411	PHARMACEUTICAL ANALYSIS-IV	5.08%	3.39%	8.47%	15.25%	3.39%
PH412	PHARMACEUTICAL TECHNOLOGY-II	5.08%	11.86%	16.94%	1.69%	3.39%
PH413	NOVEL DRUG DELIVERY SYSTEM	5.08%	11.86%	16.94%	5.08%	1.69%
MB402	ENTERPRENURESHIP FOR PHARMA PROFESSIONAL	3.39%	20.34%	23.73%		1.69%
PH414.01	ELECTIVE-II (PHARMACEUTICAL INSTRUMENTATION & TECHNOLOGY-II)			0.00%		
PH414.02	ELECTIVE-II (PHARMACEUTICAL DOCUMENTATION-II)			0.00%		
PH414.03	ELECTIVE-II (PHARMACEUTICAL MARKETING-II)			0.00%		
MB402 (P)	ENTERPRENURESHIP FOR PHARMA PROFESSIONAL (P)			0.00%		

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Based on Percentage - Sem - 8 - 2015-16 (Practical Courses)						
Subject Code		AA	AB		DD	FF
		PR	PR	Total	PR	PR
PH408	CLINICAL PHARMACY & PHARMACOTHERPUTICS-II		11.86%	11.86%	1.69%	1.69%
PH409	HERBAL DRUGS TECHNOLOGY-II			0.00%		
PH410	MEDICINAL CHEMISTRY-IV	10.17%	33.90%	44.07%		1.69%
PH411	PHARMACEUTICAL ANALYSIS-IV			0.00%		
PH412	PHARMACEUTICAL TECHNOLOGY-II	6.78%	18.64%	25.42%		1.69%
PH413	NOVEL DRUG DELIVERY SYSTEM			0.00%		
MB402	ENTERPRENURESHIP FOR PHARMA PROFESSIONAL	10.17%	11.86%	22.03%		1.69%
PH414.01	ELECTIVE-II (PHARMACEUTICAL INSTRUMENTATION & TECHNOLOGY-II)		14.71%	14.71%	5.88%	2.94%
PH414.02	ELECTIVE-II (PHARMACEUTICAL DOCUMENTATION-II)	25.00%	70.00%	95.00%		
PH414.03	ELECTIVE-II (PHARMACEUTICAL MARKETING-II)			0.00%		
MB402 (P)	ENTERPRENURESHIP FOR PHARMA PROFESSIONAL (P)	94.92%	1.69%	96.61%		1.69%

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Enclosure - VII

Vision and Mission of the Institute

Vision

To Become a Premier Pharma Institute By Creating World Class Pharmacists And Researchers For Dissemination And Creation Of Knowledge

Mission:

To Develop Entrepreneurial Pharmacist with a Penchant for Research and Development

Programme Education Objectives (PEO)

1. To disseminate knowledge and train in skill development in all areas of pharmacy, which will be helpful to students for their future professional development, as well as in advance studies.
2. To encourage students for self learning through modern information resources
3. To make students aware about advances in pharmacy and to orient towards socially relevant research and development.
4. To develop effective communication and critical thinking abilities for societal responsibilities.
5. To nurture and facilitate Entrepreneurial capabilities and expose to them the opportunities available as an Entrepreneur

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BASIC MATHEMATICS (MA121)
(Theory)
B.Pharm 1st Semester

Credits: 3 (Theory) Contact Hours per week: 3 (Theory)

Objective of the Course: To introduce the basic concepts of Mathematics to students passing HSC with B-group.

Pre-requisite: No additional Pre-requisite required.

Methodology: The emphasis during Lecture sessions will be on Understanding of Concepts rather than on complexities of Computational Techniques. . Relevant illustrations will be provided from the Real World processes. Sufficient home assignments will be given to the students which will test their fundamentals and ability to relate Mathematical concepts with reality. Tutorials for practicing of solving mathematical problems discussed in lectures will be conducted.

Outline of the Course

No.	Unit	Minimum No. of Contact Hours	Approx. Weightage %
1	Sets, Relations and Functions	6	14
2	Trigonometry	8	18
3	Limit, Continuity and Differentiation	9	20
4	Integration	8	18
5	Determinants and Matrices	7	15
6	Equations and their solutions	7	15
Total		45	100 %

Detailed Syllabus:

No.	Unit details	Contact hours	Approx. Weightage %
1	Sets, Relations and Functions	6	14
1.1	Sets, Number systems (Real and Complex numbers)		
1.2	Cartesian Product of sets, Relation		
1.3	Functions and their types		
1.4	Types of function: One-One, Many-One, into, onto		
1.5	Classification of function : Algebraic , Transcendental-exponential and logarithmic functions		
1.6	Visualization of graphs of standard functions		
1.7	Application of logarithms in pharmaceutical computations		
2	Trigonometry	8	18
2.1	Measurement of angle and trigonometric functions		
2.2	Trigonometric -ratios, addition, subtraction and transformation formulae,		
2.3	Trigonometric -ratios of multiple, submultiple,		
2.4	Allied and certain angles.		
3	Limit, Continuity and Differentiation	9	20
3.1	Limits of functions and evaluation		
3.2	Continuity of functions		
3.4	Differentiation		
3.5	Derivatives of Standard Functions and evaluation		
3.7	Derivative as a Rate of Change		

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3.8	Visualization of graphs of Continuous and Differentiable functions		
4	Integration	8	18
4.1	Indefinite Integrals (Primitives / Anti derivatives)		
4.2	Primitives of Standard Functions		
4.3	Methods of Integration		
4.4	Definite Integral		
4.5	Integration as Area under the curve		
5	Determinants and Matrices	7	15
5.1	Determinants (up to order 3) and their properties		
5.2	Cofactor expansion		
5.3	Matrices		
5.3	Matrix Operations		
5.4	Properties of Matrix Operations		
5.5	Some special matrices		
6	Equations and their solutions:	7	15
6.1	Polynomial equations in single variables and solution		
6.2	Quadratic equations and their solutions		
6.4	Solution of System of Linear equations using Cramer's rule and Matrix Inversion		
6.5	Fundamental theorem of algebra		

Instructional Method and Pedagogy:

- At the start of course, the course delivery pattern, prerequisite of the subject will be discussed.
- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Attendance is compulsory in lectures/laboratory which carries a 5% component of the overall evaluation.
- Minimum two internal exams will be conducted and average of two will be considered as a part of 20% overall evaluation.
- Assignments based on course content will be given to the students at the end of each unit/topic and will be evaluated at regular interval. It carries a weight age of 5%.

Recommended study materials:

1. Kreyszig, Erwin. Advanced engineering mathematics. John Wiley & Sons, 2010.
2. Stewart, James. "Calculus: Early Transcendentals, 6E." Belmont, CA: Thompson Brooks/Cole (2006).
3. Wylie, C. R., and L. C. Barrett. "Advanced Engineering Mathematics." McGraw-Hill,1982
4. Greenberg, Michael D. Advanced engineering mathematics. Prentice-Hall, 1988.
5. Thomas, G. B., and R. L. Finney. "Calculus with Analytic Geometry (9th Edition), 1996.", Addison Wesley Publishing.
6. Stewart, James, Lothar Redlin, and Saleem Watson. Algebra and trigonometry. Nelson Education, 2015.

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Enclosure VIII

ADVANCED MATHEMATICS (MAI22)
(Theory)
B.Pharm 2nd Semester

Credits: 3 (Theory) Contact Hours per week: 3 (Theory)

Objective of the Course: To introduce the basic concepts of Mathematics to students passing HSC with B-group.

Pre-requisite: No additional Pre-requisite required.

Methodology: The emphasis during Lecture sessions will be on Understanding of Concepts rather than on complexities of Computational Techniques. Relevant illustrations will be provided from the Real World processes. Sufficient home assignments will be given to the students which will test their fundamentals and ability to relate Mathematical concepts with reality. Tutorials for practicing of solving mathematical problems discussed in lectures will be conducted.

Outline of the Course:

No.	Unit	Minimum No. of Contact Hours	Approx. Weightage %
1	Mean value theorems and expansion of functions	06	14
2	Ordinary Differential Equations	08	18
3	Linear Differential Equations	06	14
4	Mathematical modelling	10	20
5	Analytical Plans Geometry	08	18
6	Basic Statistics	07	16
Total		45	100 %

Detailed Syllabus:

No.	Unit details	Contact hours	Approx. Weightage %
1	Mean value theorems and expansion of functions	06	14
1.1	Differentiation of functions		
1.2	Roll's theorem, Lagrange's and Cauchy mean value theorems		
1.3	Taylor Series Expansion and Maclaurin Series Expansion		
2	Ordinary Differential Equations	08	18
2.1	Introduction to ODE		
2.2	General and particular solutions		
2.3	Methods of variable separable and Homogeneous method		
2.4	Linear and Exact differential equations		
3	Linear Differential Equations	06	14
3.1	Complementary function and particular integral		
3.2	LDE of higher order with constant coefficients		
3.3	Methods for finding particular integrals by variation of parameters		
4	Mathematical modelling:	10	20
4.1	Introduction to mathematical models		
4.2	Growth of bacteria , rate of decay		

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4.3	Newton's law of cooling, diffusion and Fick's law of diffusion		
4.4	Spread of infectious diseases		
5	Analytical Plane Geometry:	08	18
5.1	Cartesian co-ordinates		
5.2	Distance between two points, area of triangle, slope of a line		
5.3	Equation of straight line in plane: Two-point form, intercept form, slope-intercept form, slope-point form		
5.4	Parallel and Perpendicular lines		
6	Basic Statistics	07	16
6.1	Ungrouped and Grouped data		
6.2	Diagrammatic Representation of Data		
6.3	Measures of Central Tendency		
6.4	Measures of Dispersion		

Instructional Method and Pedagogy:

- At the start of course, the course delivery pattern, prerequisite of the subject will be discussed.
- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Attendance is compulsory in lectures/laboratory which carries a 5% component of the overall evaluation.
- Minimum two internal exams will be conducted and average of two will be considered as a part of 20% overall evaluation.
- Assignments based on course content will be given to the students at the end of each unit/topic and will be evaluated at regular interval. It carries a weightage of 5%.

Recommended study materials:

1. Kreyszig, Erwin. Advanced engineering mathematics. John Wiley & Sons, 2010.
2. Narayan, Shanti. Integral calculus. S. Chand, 2005.
3. Narayan, Shanti, and P. K. Mittal. Differential calculus. Shyamlal Charitable Trust, 1942.
4. Stewart, James. "Calculus: Early Transcendentals, 6E." Belmont, CA: Thompson Brooks/Cole (2006).
5. Wylie, C. R., and L. C. Barrett. "Advanced Engineering Mathematics." McGraw-Hill,1982
6. Greenberg, Michael D. Advanced engineering mathematics. Prentice-Hall, 1988.
7. Thomas, G. B., and R. L. Finney. "Calculus with Analytic Geometry (9th Edition), 1996.", Addison Wesley Publishing
8. Stewart, James, Lothar Redlin, and Saleem Watson. Algebra and trigonometry. Nelson Education, 2015.

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Electives for B.Pharm Programme

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Scehme of Teaching and Evaluation for Elective Courses

Semester-6
Scheme of Teaching

Sr. No.	Course Code	Course Name	Contact hours per week		Credit	
			Theory	Practical	Theory	Practical
1	PH326.1	Pharmacy Practice - I	2	---	2	---
2	PH326.2	Herbal Formulations- I	2	---	2	---
3	PH326.3	Production Of Bulk Drugs And Drug Intermediates I	2	---	2	---
4	PH326.4	Pharmaceutical Quality Assurance And Quality Control - I	2	---	2	---
5	PH326.5	Drug Regulatory Affairs- I	2	---	2	---
6	PH326.6	Sterile Product Techonology- I				

Scheme of Evaluation

Course Code	Course Name	Theory			Practical		
		University	Institute	Total	University	Institute	Total
PH326.1	Pharmacy Practice - I	50	50	100	---	---	---
PH326.2	Herbal Formulations- I	50	50	100	---	---	---
PH326.3	Production Of Bulk Drugs And Drug Intermediates I	50	50	100	---	---	---
PH326.4	Pharmaceutical Quality Assurance And Quality Control - I	50	50	100	---	---	---
PH326.5	Drug Regulatory Affairs- I	50	50	100	---	---	---
PH326.6	Sterile Product Techonology- I	50	50	100	---	---	---

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Semester-7

Scheme of Teaching

Sr. No.	Course Code	Course Name	Contact hours per week		Credit	
			Theory	Practical	Theory	Practical
1	PH420.1	Pharmacy Practice - II	2	---	2	---
2	PH420.2	Herbal Formulations- II	2	---	2	---
3	PH420.3	Production Of Bulk Drugs And Drug Intermediates II	2	---	2	---
4	PH420.4	Pharmaceutical Quality Assurance And Quality Control - II	2	---	2	---
5	PH420.5	Drug Regulatory Affairs- II	2	---	2	---
6	PH420.6	Sterile Product Techonology- II				

Scheme of Evaluation

Course Code	Course Name	Theory			Practical		
		University	Institute	Total	University	Institute	Total
PH420.1	Pharmacy Practice - II	50	50	100	---	---	---
PH420.2	Herbal Formulations- II	50	50	100	---	---	---
PH420.3	Production Of Bulk Drugs And Drug Intermediates II	50	50	100	---	---	---
PH420.4	Pharmaceutical Quality Assurance And Quality Control - II	50	50	100	---	---	---
PH420.5	Drug Regulatory Affairs- II	50	50	100	---	---	---
PH420.6	Sterile Product Techonology - II	50	50	100	---	---	---

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Semerstser 8
Scheme of Teaching

Sr. No.	Course Code	Course Name	Contact hours per week		Credit	
			Practical	Project	Practical	Project
1	PH426.1	Pharmacy Practice - III	3	3	3	3
2	PH426.2	Herbal Formulations- III	3	3	3	3
3	PH426.3	Production Of Bulk Drugs And Drug Intermediates III	3	3	3	3
4	PH426.4	Pharmaceutical Quality Assurance And Quality Control - III	3	3	3	3
5	PH426.5	Drug Regulatory Affairs- III	3	3	3	3
6	PH426.6	Sterile Product Techonology - III	3	3	3	3

Scheme of Evaluation

Course Code	Course Name	Practical			Project		
		University	Institute	Total	University	Institute	Total
PH426.1	Pharmacy Practice - III	50	50	100	50	50	100
PH426.2	Herbal Formulations- III	50	50	100	50	50	100
PH426.3	Production Of Bulk Drugs And Drug Intermediates III	50	50	100	50	50	100
PH426.4	Pharmaceutical Quality Assurance And Quality Control - III	50	50	100	50	50	100
PH426.5	Drug Regulatory Affairs- III	50	50	100	50	50	100
PH426.6	Sterile Product Techonology - III	50	50	100	50	50	100

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Elective on
Pharmacy Practice

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Semester-VI

Pharmacy Practice - I (Elective-I) (PH326.1)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objective of the Course

Students will gain a broader understanding of pharmacy practice, standards and regulations. The goal of this course is for each student to appreciate the clinical and operational aspects of pharmacy practice

Student Learning Outcomes / Objectives

At the end of the course, the student will be able to understand

- The concept of Pharmacy practice and its scope
- Students understand the role of the pharmacist in epidemiology study and development and concept of clinical informatics
- Able to learn skill require to provide drug and poison information to healthcare professionals

Instructional Methods and Pedagogy:

The content of the syllabus would be transmitted through different pedagogy tools, as follows:

Sr.No	Particular	Hours Allotted
1	Classroom interaction	13
2	Group discussion	5
3	Seminar/Assisgnment	5
4	Case studies	7

Outline of course:

No.	Unit	Minimum No. of Contact Hours Approx.	Weight age %
1	Introduction to Pharmacy practice	05	17
2	Public Health & Epidemiology	10	33
3	Drug & Poison Information	08	27
4	Advances in clinical pharmacy informatics	07	23
	Total	**30**	**100%**

Detailed Syllabus

Sr no	Unit Details	No. of Hours
1	Introduction to Pharmacy practice: Scope in India & international prospectives	05
2	Public Health & Epidemiology: Introduction and advance pharmacopeidemiology study	10
3	Drug & Poison Information: Drug information resources introduction	08
4	Advances in clinical pharmacy informatics: introduction to informatics tools use in Healthcare	07

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References:

1. A Textbook of Clinical Pharmacy Practice: G. Parthasarathi, Karin Nyfort-Hansen and Milap Nahata, Universities Press.
2. Practice of Hospital Clinical and community pharmacy Mohd Aqil
3. http:// www.who.int (World heath organization guidelines for poison control)
4. http://www.nhscareers.nhs.uk/
5. http://www.healthcare-informatics.com/
6. Adam Woolley. A guideline to Practical Toxicology: Evaluation, prediction and risk. Second edition, Informa Healthcare.
7. American Society of Health-System Pharmacists.Mission statement of the American Society of HealthSystem Pharmacists. Am J Health-Syst Pharm
8. Hospital Pharmacy. Mukul Singh, Sujata K. Dass, Shree Publisheres & Distributers
9. Hospital & Community Pharmacy by Ms. Anuja Kukkarni & Mr. Rajesh B. Patil.
10. http://www.ashp.org
11. http://apps.who.int/medicinedocs/documents/s19622en/s19622en.pdf

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Semester-VII

Pharmacy Practice -II (Elective-II) (PII420.1)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objective of the Course: Students will gain a broader understanding of pharmacy practice, standards and regulations. The goal of this course is for each student to appreciate the clinical and operational aspects of pharmacy practice

Student Learning Outcomes / Objectives: At the end of the course, the student will be able to understand

- The concept of health economics
- Students understand the role of the pharmacist in Ethics and roles in Ethical issues in pharmacy practice research
- Students can develop skills of research in clinical pharmacy practice

Instructional Methods and Pedagogy:

The content of the syllabus would be transmitted through different pedagogy tools, as follows:

Sr.No	Particular	Hours Allotted
1	Classroom interaction	13
2	Group discussion	5
3	Seminar/Assisgnment	5
4	Case studies /Audio Visual	7

Outline of course:

No.	Unit	Minimum No. of Contact Hours Approx.	Weight age %
1	Role of Pharmacist in Healthcare research, policy and economics	08	25
2	Ethical issues in clinical pharmacy practice research	08	25
3	Research in clinical pharmacy practice	14	50
	Total	**30**	**100%**

Detailed Syllabus

Sr no	Unit Details	No. of Hours
1	Role of Pharmacist in Healthcare research, policy and economics: Pharmacist or clinical pharmacist involvement in framing health care policy in various countries	08
2	Ethical issues in clinical pharmacy practice research:History, Codes, declarations and guidelines, basic principle of research, roles and responsibilities of ethics committee	08
3	Research in clinical pharmacy practice:Types of research, role of Pharmacist in clinical practice research	14

References:

1. A Textbook of Clinical Pharmacy Practice: G. Parthasarathi, Karin Nyfort-Hansen and Milap Nahata, Universities Press.

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2. Practice of Hospital Clinical and community pharmacy, By Mohd Aqil.
3. Indian Guidelines for Ethical conduct of research in Human Subjects
4. Developing Pharamcy Practice: A focus on patient care. Handbook 2006 edition.
5. Research, review and other literature from internet sources

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Semester-VIII

Pharmacy Practice - III (PH426.1)

Credits: 3 (Practical) **Contact Hours per week: 3(Practical)**
Credits: 3 (Project) **Contact Hours per week: 3 (Project)**

Students learning outcomes/objectives:
The aim of this practical is to - help you get a training period in a professional manner - help to understand the different functions and services provided by the hospital pharmacy - help students use different sources of drug information and initiate into the concept of Pharmacy practice - help to gain knowledge and practical tools for future professional career

Instructional Methods and Pedagogy:
- Lab Hours / Practicals (15 hours)
- Case studies (15 hours)
- Interaction with members of healthcare team at Hospital (15 hours)

List Practical:

Sr.No	Aim of Practical
1	To Familiarize with the functions of the hospital and the pharmacy department.
2	To understand different drug information resources and exercise based on it
3	To study Medication Use Processes with the help of case study
4	To study medication error and visit to hospital and evaluate cases related to different types of error
5	To study Drug Use Management and to study role of Pharmacist in formulary & DTC preparation.
6	To study drug therapy monitoring & to understand concept of ward round
7	To study concept of appropriate & rational use of medicine
8	To study main economic indicators of the hospital pharmacy
9	To study Drug information chart review and medical counseling
10	To study medical literature preparation and review for rationality

Project Guidelines:
Individual /Group projects will be given to the students. The project can be a minor research / field work type, which could be conducted in-house or the students can be deputed for the same in any recognized academic, research or clinical organization.

Sr. No	Work	Hours allotted
1	Discussion with Mentor	10
2	Experimental project /Field work	25
3	Write up, analysis of data and compilation.	10

Proposed Project Area
1. Survey based: Survey of Incidence, prevalence and occurrence of diseases or any condition (field work)
2. Meta analysis
3. Drug utilization
4. Drug safety, Pharmacovigilance
5. Pharmacoepidemiology study
6. Risk factor identification

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7. Pharmacist role in Hospital (ward round)
8. Drug information bases
9. Patient Counseling
10. E Prinscribing
11. Essential drug list preparation
12. Formulary preparation, audit and comparison
13. Softwares used in Health services
14. Lab data interpretation
15. Medication error
16. Drug interaction

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Elective on
Herbal Formulations

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SEMESTER-6
HERBAL FORMULATIONS-I (PH326.2)

Credits: 2 **Contact Hours per week: 2**

Objective of the Course:
To impart knowledge about role of herbal drugs in health care. Various approaches to be put up to utilize herbs as medicines. Students will also be exposed to different methods proposed to evaluate herbal raw materials.

Student Learning Outcomes / Objectives:
At the end of the course, the student should understand importance of herbal drugs.
The students are expected to

- Acquire the knowledge about importance of herbal medicine.
- Different methods for evaluation of herbal raw material.
- Role of herbal medicine in worldwide healthcare.

Instructional Methods and Pedagogy:
The content of syllabus would be delivered by following pedagogy,

Sr. No.	Particular	Hours Allotted
1	Classroom interaction	15
2	Group discussion	5
3	Seminar/Assignment	5
4	Skill development exercise	5

Outline of the Course:

No.	Unit	Minimum Contact Hours	Approx. weightage %
1	Herbal materials and its utilization worldwide.	4	15
2	Herbal raw materials and quality assessment	8	25
3	**Manufacturing of perfumes and fragrances.**	8	25
4	Regulatory status of herbal drugs worldwide.	10	35
	Total	**30**	**100**

Detailed Syllabus:

No.	Unit details	Contact Hours	References
1	**Herbal materials and their utilization worldwide.** Scenario of utilization of herbal drugs in India and worldwide as medicine as well as in cosmetics .	4	2,4,5
2	**Herbal raw materials and quality assessment** Herbal raw materials, their procurement, storage and quality evaluation.	8	1,5
3	**Manufacturing of perfumes and fragrances.** Present scenario and status of natural perfumes worldwide. Different extraction and isolation processes of isolating fragrant principles from plants. Manufacturing and evaluation of perfumes.	8	3, 4
4	**Regulatory status of herbal drugs worldwide.** GMP for Herbal and Ayurvedic Formulations. Schedule T of Drugs & Cosmetics act. Regulatory guideline for herbal drugs.	10	1,5

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Recommended study materials:

1. WHO guidelines on good manufacturing practices (GMP) for herbal medicines
2. Herbal Drug Industry. Chief Editor R.D. Chaudhary, 1st Edition, 1996. Eastern Publishers, New Delhi.
3. Perfumery technology-Art :science : Industry, by F.V. Wells and Marcel Billot, 2nd edition
4. Poucher's Perfumes, Cosmetics and Soaps, H. Butler, 10th edition, Kluwer Academic Publishers
5. Quality Control of Herbal Drugs: Mukherji P. K., Business Horizon Pharma. Publishers, 1st Edition, 2002.

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SEMESTER-7
HERBAL FORMULATIONS-II (PH 420.2)

Credits: 2 **Contact Hours per week: 2**

Objective of the Course:
The course is designed to incorporate application of herbs in therapeutical as well as cosmetic formulations

Student Learning Outcomes / Objectives:
At the end of the course, the student should understand the demand of herbal drugs and excipients.
The students are expected to

- Development of Rational formulation

Instructional Methods and Pedagogy:
The content of syllabus would be delivered by following pedagogy,

Sr. No.	Particular	Hours Allotted
1	Classroom interaction	15
2	Group discussion	5
3	Seminar/Assignment	5
4	Skill development exercise	5

Outline of the Course:

No.	Unit	Minimum No. of Contact Hours	Approx. weightage %
1	Preformulation and Formulation Design	5	25
2	Preparation of Herbal Therapeutic Formulations	15	40
3	Herbal Cosmetics and Nutraceuticals	10	35
Total		**30**	**100**

Detailed Syllabus:

No.	Unit details	Contact Hours	References
1	Concept of preformulations studies and fundamentals of formulation design.	5	1,2,3,4,6
2	Herbal formulations- topical, tablets, syrups, dentrifices	15	2,3,4,5,6
3	Herbal cosmetics- skin care and hair care.	10	5,6

Recommended study materials:

1. Harry's Cosmeticology, Radelph Harry, 8th edition, Chemical Publishing Company.
2. Perfumes, Soaps, Detergents and Cosmetics, S.C. Bhatia, 1st edition, CBS publishers
3. Handbook of Cosmetic Science and Technology, Andre Barel, Marc Paye, Howard I. Maibach, CRC Press.
4. Herbal drug technology, S. S. Agrawal and M. Paridhavi, Univeristies Press, 1st Edition, 2007.
5. Quality Control of Herbal Drugs: Mukherji P. K., Business Horizon Pharma. Publishers, 1st Edition, 2002.
6. Indian Herbal Pharmacopoeia, Volume I and II, 1999. A Joint Publication of IDMA and RRL, Jammu –Tawi.

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SEMESTER-8
HERBAL FORMULATIONS-III (PH426.2)

Credits: 3 (Practical) **Contact Hours per week: 3(Practical)**
Credits: 3 (Project) **Contact Hours per week: 3 (Project)**

Objective of the Course:
The course focuses on imparting the skill of development of rational formulation and preparation in laboratory including evaluation of prepared formulations.

Student Learning Outcomes / Objectives:
At the end of the course, the student should be able to understand the fundamental of rational behind selection of appropriate herbal drugs and extracts to develop a new formulation. He/She should be able to evaluate the formulation as well.

Instructional Methods and Pedagogy:
The content of syllabus would be delivered by

- Class room teaching and discussion
- Skill development exercise
- Theoretical project or seminar and their presentation
- Practical related to development and standardization of herbal formulation and evaluation of marketed Ayurveda formulation.

Detailed Syllabus Project: (03 Hr. /Week)

Project Guidelines:
Individual /Group projects will be given to the students. The project can be a minor research / field work type, which could be conducted in-house or the students can be deputed for the same in any recognized academic, research or clinical organization.

Sr. No	Work	Hours allotted
1	Discussion with Mentor	10
2	Experimental project /Field work	25
3	Write up, analysis of data and compilation.	10

The project will be based on following topics;

1. Preparation and Evaluation of Herbal Formulation and Herbal Cosmetics
2. Comparative Evaluation of Marketed Herbal Formulations
3. Market Survey on Herbal Formulation and Herbal Cosmetics
4. Branding and Marketing of Herbal Formulations
5. Clinical and Preclinical Reviews of herbal Drugs and Herbal Formulations
6. Regulatory status of Herbal Formulations in Various Countries

Practicals to be offered:

No.	Aim of the Practical
1	Formulation development & standardization of herbal cream.
2	Formulation development & standardization of herbal gel.
3	Formulation development & standardization of herbal shampoo.
4	Formulation development & standardization of herbal toothpaste.
5	Formulation development & standardization of herbal tablet.
6	Formulation development & standardization of herbal syrup.
7	Evaluation of marketed Ayurveda formulation.

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Recommended study materials:

1. Herbal Drug Industry. Chief Editor R.D. Chaudhary, 1st Edition, 1996. Eastern Publishers, New Delhi.
2. The ayurvedic Formulary of India, Part I and II, Department of Indian system of Medicine and Homoeopathy, Govt, of India, 1st English Edition, 2000.
3. Herbal drug technology, S. S. Agrawal and M. Paridhavi, Univeristies Press, 1st Edition, 2007.
4. Handbook of Cosmetic Science and Technology, Andre Barel, Marc Paye, Howard I. Maibach, CRC Press.
5. Cosmetic technology, Nanda S, Nanda A, Khar RK., Birla Publications Pvt. Ltd
6. Cosmetics: Science and Technology, Balsam S.M. and Sagarin Edward, 2nd Ed, Wiley Interscience.

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Elective On
Production of Bulk Drug and Drug Intermediates

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Semester-VI

Production of Bulk Drugs and Drug Intermediates I (PH326.3)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objective of the Course:
The course is designed to make students familiar with various approaches used for production of bulk drugs and intermediates. The course will also provide knowledge regarding various processes and parameters useful for the same.

Students learning outcomes/objectives:
By the end of this course, the student should have a good understanding of the basic concepts of process chemistry. They are expected to gain the knowledge of route selection, processing and optimization of various synthetic methodologies. They would also understand various processes used for bulk drug production.

Instructional Methods and Pedagogy:
- Interactive Teaching (15 hr)
- Discussion (10 hr)
- Case studies (05 hr)

Outline of the Course:

No.	Unit	Minimum Contact Hours	Approx. weightage %
1	Basic Concepts of Process Chemistry	20	67
2	Processing techniques in bulk drugs and intermediate production	07	23
3	WHO Good Manufacturing Practices for active pharmaceutical ingredients	03	10
Total		**30**	**100**

Detailed Syllabus (Theory):

No.	Unit details	Contact Hours	References
1	**Basic Concepts of Process Chemistry** • Concept of Basic Process Research and implication on Process Research and Development & Production • Synthetic Route Finding and Selection – Concept, Application and Case Studies. • Synthone approaches applied to drugs and drug intermediates. • Knowledge of the concepts of route enabling and synthesis optimization: "green" choice of solvent, reagent, catalysts, etc. • Knowledge of applications & the use of catalysis in PRD	20	1,2,3,4,5
2	**Processing techniques in bulk drugs and intermediate production** Liquid- Liquid Processing, Evaporation And Fractional Distillation, Adsorption From Solution, Crystallization From Solution, Solid – Liquid Processing and Separation, Solid Finishing – Drying.	07	1,2,3,4,5
3	WHO Good Manufacturing Practices for active pharmaceutical ingredients	03	6,7

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Recommended study materials:

1. Process Chemistry in the Pharmaceutical Industry, Volume 1edited by Kumar Gadamasetti
2. N. G. Anderson, "Practical Process Research & Development", Academic Press 2000.
3. O. Repic, "Principles of Process Research and Chemical Development in the Pharmaceutical Industry, Wiley 1998.
4. N. Yasuda, "The Art of Process Chemistry", Wiley 2010
5. R.A. Sheldon, I. Arends, U. Hanefeld, "Green Chemistry & Catalysis", Wiley 2007
6. WHO Guideline.
7. ICH Guidelines.

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Semester-VII

Production of Bulk Drugs and Drug Intermediates II (PH420.3)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objective of the Course:
The course is designed to make students familiar with various types or reactions and their processing, and unit operation related to those reactions. It will also explain the students for applicability of the mentioned reaction.

Students learning outcomes/objectives:
By the end of this course, the students would become familiar with the various types of reactions utilized for bulk drugs and intermediate production. They will also learn newer synthetic technologies which would me time saving and green and their applications.

Instructional Methods and Pedagogy:
- Interactive Teaching (15 hours)
- Discussion (10 hours)
- Case studies (5 hours)

Outline of the Course:

No.	Unit	Minimum Contact Hours	Approx. weightage %
1	Understanding of concepts of process chemistry with references to various unit processes	30	100
Total		**30**	**100**

Detailed Syllabus (Theory):

No.	Unit details	Contact Hours	References
1	**Understanding of concepts of process chemistry with references to various unit processes** • Route Enabling & Lab Optimization • Kinetics & Mechanism evaluation in PRD • Optimization by understanding impurities • New synthesis technologies like solid phase chemistry, flow chemistry, micro wave and aqua Chemistry • Advanced Asymmetric Synthesis & Catalysis • Knowledge of the concepts of asymmetric synthesis & applications • Applications of enzymes in organic synthesis • Understanding the above mentioned concepts with reference to unit process like: 1. Alkylation 2. Amination 3. Condensation and Addition 4. Esterification 5. Friedel-Crafts Reactions 6. Halogenations 7. Hydrogenation 8. Oxidation	30	1,2,3,4,5

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Recommended study materials:

1. Process Chemistry in the Pharmaceutical Industry, Volume 1edited by Kumar Gadamasetti
2. N. G. Anderson, "Practical Process Research & Development", Academic Press 2000.
3. O. Repic, "Principles of Process Research and Chemical Development in the Pharmaceutical Industry, Wiley 1998.
4. N. Yasuda, "The Art of Process Chemistry", Wiley 2010
5. R.A. Sheldon, I. Arends, U. Hanefeld, "Green Chemistry & Catalysis", Wiley 2007

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Semester-VIII

Production of Bulk Drugs and Drug Intermediates III (PH426.3)

Credits: 3 (Practical) **Contact Hours per week: 3 (Practical)**
: 3 (Projects) **: 3 (Projects)**

Objective of the Course:
The course is designed to make students familiar with various types or reactions and their processing, and unit operation related to those reactions. It will also explain the students for applicability of the mentioned reaction.

Students learning outcomes/objectives:
By the end of this course, the students would become familiar with the various types of reactions utilized for bulk drugs and intermediate production. They will also learn newer synthetic technologies which would me time saving and green and their applications.

Instructional Methods and Pedagogy:
- Discussion and Case Study (20 hr.)
- ICT Based Demonstration of various Bulk Drug Processes (10 hr.)
- Interaction with Industrial Expert and industrial visit (15 hr.)
- Practical (45 Hrs.)

Detailed Syllabus of Project: (03 Hr. /Week)

Project Guidelines:
Individual /Group projects will be given to the students. The project can be a minor research / field work type, which could be conducted in-house or the students can be deputed for the same in any recognized academic, research or clinical organization.

Sr. No	Work	Hours allotted
1	Discussion with Mentor	10
2	Experimental project /Field work	25
3	Write up, analysis of data and compilation.	10

The project will be based on following topics;
1. Solvent Purification Techniques
2. Crystallization Techniques
3. Structural Elucidation of Organic Compounds
4. Bulk Drug Process and Manufacturing: Case Study
5. Application of Green Chemistry
6. Application of Microwave Synthesis and its advantages over Conventional synthesis
7. Importance of QbD and DOE in API Manufacturing
8. Stereochemistry and Chiral Separation of Enantiomer
9. Synthon Approach
10. Protection and Deprotection Approach
11. Synthesis of API's (Laboratory Work)

Detailed Syllabus (Practical):(03 Hr./Week)

Topic No.	Aim of the Practical
1	Synthesis of Aspirin form salicylic Acid by Common synthetic route and Microwave Approach and compare the Practical yields.
2	Synthesis by Common synthetic route and reaction in aqueous medium and compare the Practical yields.
3	Use of different solvents for Synthesis (01 Practical)
4	Case study base practical (Bulk Drug Production Process of any two API's)

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5	Reaction in Aqueous Medium (01 Practical)
6	Solvent Recovery Techniques (01 Practical)
7	Reaction by use of different Catalyst (Esterification) (01 Practical)
8	Crystallization from different solvents (02 Practical)
9	Structural Elucidation of Organic Compounds (02 Practical's)

References:

1. Vogel's Text Book of Practical Organic Chemistry- Brian Furniss, Antony Hannaford, Peter Smith, Austrin (Eds), 5th edition, ELBS Publication, Singapore, 1997.
2. Process Chemistry in the Pharmaceutical Industry, Volume 1edited by Kumar Gadamasetti
3. N. G. Anderson, "Practical Process Research & Development", Academic Press 2000.
4. O. Repic, "Principles of Process Research and Chemical Development in the Pharmaceutical Industry, Wiley 1998.
5. N. Yasuda, "The Art of Process Chemistry", Wiley 2010
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Elective on
Pharmaceutical Quality Assurance and Quality Control

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Semester-VI

Pharmaceutical Quality Assurance and Quality Control – I (PH326.4)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objective of the course:

- To learn the concept of QA-QC-GMP-TQM, GLP-ICH.
- To understand the Quality Control Laboratory and its activities.
- To introduce the basic concepts of GLP and its implementation.
- To understand the In-Process Quality Control their Basic Concept, IPQC tests for Tablets and Capsules

Students learning outcomes/objectives:

Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)

- Concepts of quality control and quality assurance and its implementation
- Regulatory guidance's and guidelines like ICH and other relevant documents
- Good Laboratory Practices, Good Manufacturing Practices(GMP)
- Quality Control Laboratory and its activities

Instructional methods and pedagogy:

- Interactive Teaching (15 hours)
- Discussion (07 hours)
- Case studies (05 hours)
- Visit to Pharmaceutical Manufacturing Plant (03 hours)

Outline Syllabus

No.	Unit	Minimum Contact Hours	Approx. weightage %
1	Concept and Philosophy of Quality, Quality Assurance and Quality Control	03	10
2	Interrelation of QA-QC-GMP-TQM, GLP	09	30
3	Quality Control Laboratory and its activities	09	30
4	Introduction to ICH and its guidelines for Quality	03	10
5	In-Process Quality Control:	06	20
Total		30	100

Detailed Syllabus (Theory):

No.	Unit	Minimum Contact Hours	References
1	Concept and Philosophy of Quality, Quality Assurance and Quality Control, Total Quality Management (TQM), Good Manufacturing Practices(GMP), cGMP, Good Laboratory Practices (GLP) in pharmaceutical and healthcare industries	03	
2	Interrelation of QA-QC-GMP-TQM, GMP: Elements and Overview of Regulatory requirements, GLP: Scope, History, Elements and Schedule L1 in brief.	09	
3	Quality Control Laboratory and its activities: Lab layout, Requirements of Facilities, Equipments, Personnel, Activities such as Calibration of QC equipments, Testing Procedures, Specification.	09	
4	Introduction to ICH and its guidelines for Quality	03	
5	In-Process Quality Control: Basic Concept, IPQC tests for Tablets and Capsules.	06	

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Recommended study materials:

1. Good Manufacturing Practices for Pharmaceuticals, Sidney H. Willig, Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., New York.
2. Good Manufacturing Practices for Pharmaceuticals, Joseph D. Nally, Drugs and Pharm. Sci. Series, Vol. 169, Informa healthcare.
3. Modern Pharmaceutics, G. S, Banker & C.T. Rhodes, Drugs and Pharm. Sci. Series, Vol. 121, Maracel Dekker Inc., New York.
4. How to practice GMPs, P. P .Sharma, Vandana Publication, Delhi.
5. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series

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Semester-VII

Pharmaceutical Quality Assurance and Quality Control – II (PH420.4)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Objective of the course:

- To learn the concept of Qualification and Validation
- To train the students about the importance and requirement of good documentation practices.
- To learn about Analytical Method Validation & its Objectives, Methodology etc.
- To understand Quality Inspections and Audits.

Students learning outcomes/objectives:

Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)

- Concepts of validation and its implementation
- Documentation in Pharmaceutical Industry i.e. Protocol preparation for documentation of various types of records (BFR, MFR, Quality audit Report, SOPs, etc.)
- Analytical Method Validation
- Documentation for audits and inspection of manufacturing facilities.

Instructional methods and pedagogy:

- Interactive Teaching (15 hours)
- Discussion (07 hours)
- Case studies (05 hours)
- Visit to Pharmaceutical Manufacturing Plant (03 hours)

Outline Syllabus

No.	Unit	Minimum Contact Hours	Approx. weightage %
1	Qualification and Validation	09	30
2	Analytical Method Validation	03	10
3	Documentation in Pharmaceutical Industry	09	30
4	Quality Inspections and Audits	09	30
Total		30	100

Detailed Syllabus (Theory):

No.	Unit	Minimum Contact Hours	References
1	Qualification and Validation: Definitions, Difference between Qualification and Validation. Introduction to the basic concept of Validation in Pharmaceutical Manufacturing, Process Validation: Types, Objective, how it differs from Qualification (DQ, IQ, OQ, PQ), Validation Master Plan	09	
2	Analytical Method Validation: Objectives, Method Characteristics, Assessment Methodology	03	
3	Documentation in Pharmaceutical Industry: Good Documentation Practices, Batch Formula Record, Master Formula Record, Quality Audit Report, SOP, Certificate of Analysis, Complaint and evaluation of complaint, Handling of returned goods, Recalling and Waste Disposal.	09	
4	Quality Inspections and Audits: Definitions- Inspection, Periodic evaluation and Audit, Types, Approaches, Benefits, Audit Report, Regulatory Audit	09	
Total		30	

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Recommended study materials:

1. Pharmaceutical Process Validation, B. T. Loftus & R. A. Nash, Drugs and Pharm Sci. Series, Vol. 129, Marcel Dekker Inc., New York.
2. The Theory & Practice of Industrial Pharmacy, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master Plan, Terveeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, Carleton & Agalloco, Marcel Dekker Inc., New York.
5. Pharmaceutical Process Scale-Up", Michael Levin, Drugs and Pharm. Sci. Series, Vol. 157, Marcel Dekker Inc., New York.
6. Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition
7. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
8. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn.(1989) Marcel Dekker Inc. New York.
9. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
10. Pharmaceutical process validation (Drugs and Pharmaceuticals Series), Ira R. Berry and Robert A. Nash, 2nd Edn.(1993), Marcel Dekker Inc., New York.
11. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

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Semester-VIII

Pharmaceutical Quality Assurance and Quality Control – III (PH426.4)

Credits : 3 (Practical) **Contact Hours per week : 3 (Practical)**
: 3 (Project) **: 3 (Project)**

Objective of the course:

- To learn about pharmaceutical documentation system
- To train the students about Regulatory guidance's and guidelines like ICH, ISO 9001 and other relevant documents

Students learning outcomes/objectives:

Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)

- Preparation of SOP, validation protocol, validation report
- In-Process Quality Control tests for Tablet, Capsules etc.

Instructional methods and pedagogy:

- Lab hours (15 hours)
- Assignment (15 hours)
- Discussion (10 hours)
- Interaction with Experts from Industry (05 hours)

Syllabus

Detailed Syllabus (Practical):

Sr. No	Aim of the Practical
1	To perform IPQC tests for Tablets
2	To perform IPQC tests for capsules
3	To calibrate pH meter, analytical balance, volumetric glassware.
4	To calibrate UV spectrophotometer
5	To perform validation of autoclave and oven
6	To prepare SOP of any two analytical equipments
7	To prepare SOP of any two processing equipments
8	To prepare validation protocol.
9	To prepare validation report
10	To prepare record sheet
11	Case studies on Quality Risk Management, GMP non-compliance, Regulatory Audit
12	Any other relevant to topics covered in theory course 1 and 2 of elective on pharmaceutical quality assurance and quality control

Project:

Project Guidelines:

Individual /Group projects will be given to the students. The project can be a minor research / field work type, which could be conducted in-house or the students can be deputed for the same in any recognized academic, research or clinical organization.

Sr. No	Work	Hours allotted
1	Discussion with Mentor	10
2	Experimental project /Field work	25
3	Write up, analysis of data and compilation.	10

Students are expected to pursue a project in the broad area of quality assurance and quality control. It may be specifically on development of protocol, preparation of standard operating procedure, validation of equipment, validation of process, validation of facilities, development and validation of analytical procedure, calibration master plan, Manufacturing Risk management, pharmaceutical quality system or any other area relevant to pharmaceutical quality assurance and quality control. The project may be individual or in group.

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Recommended study materials:

1. Total Quality Management- Guiding Principle for Application, J. P. Peker, ASTM manual series, Philadelphia.
2. Total Quality Management – The Key to Business Improvemetn, Champman & Hall, Londan.
3. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
4. A guide to Total Quality Management – Kaushik Maitra and Sedhan K.Ghosh.
5. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
6. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1and Vol.2, WHO, (1999).
7. ICH guidelines

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Elective on
Drugs Regulatory Affairs

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Semester-VI

DRUG REGULATORY AFFAIRS- I (Elective-I) (PH326.5)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Course objective:

The objectives of this course are as follows:

- To get familiar with the process of getting the approval of drug in India.
- To understand provisions applicable to various regulatory agencies like USA, Australia, Europe, UK etc.
- To know the filing procedure of regulatory agencies like USA, Australia, Europe, UK etc.

Learning Outcomes

At the end of the course,

- One can know the process of product registration and marketing authorization in countries like USA, Australia, European and UK.
- Students can awake about the how the differences between the India and other countries likes USA, Australia, European and UK. Other than medicine, the registration process of medical devise, cosmetic product and biotechnological product registration process can be understood.

Outline of course:

No.	Unit	Minimum No. of Contact Hours Approx.	Weight age %
1	Drug regulatory authorities in India	05	18
2	Regulation and registration in India	13	42
3	Brief about the drug regulatory agencies in world	08	25
4	Brief study of regulatory documents	04	15
	Total	**30**	**100%**

Detailed Syllabus

Sr no	Unit Details	No. of Hours
1	Drug regulatory authorities in India- ▪ Central Drug Standard Control Organization (CDSCO) and State Food and Drug Control Administration (FDCA)	05
2	Regulation and registration of followings in India: • Drug • Medical devices • Cosmetics • Biologics & Biotechnological products	13
3	Brief about the drug regulatory agencies in world:- ▪ Medicines & Healthcare products Regulatory Agency (MHRA)- UK ▪ Therapeutic Goods Administration (TGA)-Australia ▪ European Medicines Agency (EMEA)-European ▪ Food and Drug Administration (FDA)- USA ▪ Health Canada- Canada	08
4	Brief study of regulatory documents: ▪ Common Technical Document (CTD), ▪ Electronic Common Technical Document (eCTD)	04

Pedagogy

The course will transact with aim of participation and one to one learning through active classroom interaction, group discussion and presentation mode.

- Classroom teaching :- 15 hrs
- Case study :- 05 hrs
- Group Discussions :- 05 hrs
- Students' Presentations :- 05 hrs

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Recommended study materials:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, Edited by Douglas J. Pisano and David S. Mantus, published by informa healthcare.
2. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India.
3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
4. Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices -- John J. Tobin and Gary Walsh.
5. www.mhra.gov.uk/
6. http://www.fda.gov/
7. https://www.tga.gov.au/
8. http://www.ema.europa.eu/ema/
9. http://cdsco.nic.in
10. www.hc-sc.gc.ca/
11. www.ich.org

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Semester-VII

DRUG REGULATORY AFFAIRS- II (Elective-II) (PH420.5)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Course Objectives:

- To introduce the students to the various guidelines of International Conference on Harmonization (ICH) and WHO.
- To familiar the students about ASEAN guidelines and its dossier preparation

Learning Outcomes

At the end of the course, the student should have capable:

- Understand the importance of guidelines of International Conference on Harmonization (ICH) and WHO relevant to the regulatory filing
- Preparation of dossier as per the guidelines of ASEAN countries.

Outline of course:

No.	Unit	Minimum No. of Contact Hours Approx.	Weight age %
1	International Conference on Harmonization (ICH) guidelines on stability relevant to the regulatory filing	14	47
2	WHO guidelines for the drugs and Pharmaceuticals	08	27
3	ASEAN guidelines: Study and dossier preparation as per the guidelines of ASEAN	08	26
	Total	**30**	**100%**

Detailed Syllabus

Sr no	Unit Details	No. of Hours
1	International Conference on Harmonization (ICH) guidelines on stability relevant to the regulatory filing: Stability Testing of New Drug Substances and Products Stability Testing , Photostability Testing of New Drug Substances and Products, Stability Testing for New Dosage Forms, Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products, Evaluation of Stability Data, Impurities in New Drug Substances, New Drug Products	14
2	WHO guidelines for the finished products	08
3	ASEAN guidelines: Study and dossier preparation as per the guidelines of ASEAN	08

Pedagogy:

- Classroom teaching :- 15 hrs
- Case study :- 05 hrs
- Group Discussions :- 05 hrs
- Students' Presentations :- 05 hrs

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References:

1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices By John J. Tobin and Gary Walsh
2. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus
3. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Volume 1 by Helene I. Dumitriu
4. Encyclopedia of Pharmaceutical Technology, James Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
5. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
6. **www.ich.org**
7. www.**who.int**/
8. www.**asean**.org/

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Semester-VIII
DRUG REGULATORY AFFAIRS- III (Elective-III) (PH426.5)

Credits: 3(Practical)	**Contact Hours per week: 3(Practical)**
Credits: 3 (Project)	**Contact Hours per week: 3(Project)**

Objective of the Course:
To make students familiar with different regulatory related documentation practices followed in pharmaceutical industry.
Learning Outcomes
The students are expected to learn preparations of various documents involved in pharmaceutical industry in departments of regulatory affairs.

List of Practicals
- To prepare Master formula record (MFR) and study Batch formula record (BFR) for any two formulations.
- To prepare in process quality control (IPQC) protocol for any two formulations.
- To study and understand components of clinical research protocols.
- To prepare sample stability study protocol for any two formulations.
- To prepare sample Preclinical study reports and summaries.
- To prepare package design and package inserts for any two formulations.
- To study Specification and Method of analysis protocol for any one API.
- To prepare Analytical method validation protocol.
- To prepare modules of CTD document as per guidelines of regulatory agencies of different countries.
- To analyze cases related to the regulatory affairs.
- To study sample dossier for getting approval of solid dosage form (national and/or International) and to write dossier in group of 4-5 on any selected drug product.

Project Guidelines:
- Individual /Group projects will be given to the students. The project can be a minor research / field work type, which could be conducted in-house or the students can be deputed for the same in any recognized academic, research or clinical organization.

Sr. No	Work	Hours allotted
1	Discussion with Mentor	10
2	Experimental project /Field work	25
3	Write up, analysis of data and compilation.	10

List of Projects
- Preparation of various document/s for registration of drug product in India.
- Preparation of drug master file for registration of drug in India, USA & EU.
- Analysis of cases related to the regulatory affairs.
- Preparation of modules as per ASEAN, ICH & WHO guidelines.
- Preparation of dossiers as per guidelines of regulatory agencies of different countries.

References:
1. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices By John J. Tobin and Gary Walsh
2. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Douglas J. Pisano and David S. Mantus

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3. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol. 1 by Helene I. Dumitriu
4. CGMP-a good manufacturing practice for pharmaceuticals, Manohar Potdar, Pharmamed press, 2008.
5. Validation in Pharmaceutical Industry (Concept, Approaches & Guidelines), P.P.Sharma, Vandana Publications, New Delhi.
6. Official website of regulatory agencies of different countries.

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Elective on
Sterile Products Technology

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Semester - VI

Sterile Products Technology (PH 326.6)

Credits: 2 (Theory) **Contact Hours Per Week: 2 (Theory)**

Course objective:

- To understand the basic fundamentals of sterile dosage forms.
- To know the types of sterile dosage forms used pharmaceutical field.
- To get familiar with the layout and GMP guidelines for sterile dosage forms.

Learning Outcomes:

- By the end of this course, the student should have good understanding of the basic concepts of sterile products in pharmacy.
- Students should gain knowledge of the sterile products' characteristics and their plant layout designing.

Outline of the course (Theory):

Sr. No.	Title of the unit	Minimum no. of contact hrs.	Approx. Weightage %
1	Introduction to Sterile Dosage Forms.	10	33
2	Design consideration for sterile production facility.	08	27
3	Environmental control in production of sterile dosage forms.	06	20
4	GMP Requirements for sterile products.	06	20
Total		**30**	**100%**

Detailed Syllabus

Sr. No.	Title of the Topic	Contact Hours	Reference No.
1	**Introduction to Sterile Dosage Forms:** Historical background, their importance, types with routes of administration, characteristics, WFI management.	10	1,2,3,5
2	**Design consideration for sterile production facility:** Plant Layout – small and large scale, flow of work, flow of material and flow of personnel, Instruments' location.	08	1,6
3	Environmental control in production of sterile dosage forms.	06	4
4	GMP Requirements for sterile products.	06	1,2

Pedagogy:

The course will transact with aim of participation and one to one learning through active classroom interaction, group discussion and presentation mode.

- Classroom teaching :- 15 hrs
- Case study :- 05 hrs
- Group Discussions :- 05 hrs
- Students' Presentations :- 05 hrs

Recommended Study Materials:

1. The theory and Practice of Industrial Pharmacy, Leon Lachman, Lea & Febiger, Varghese Publication House Bombay.
2. Remington's Pharmaceutical Sciences, Edited by A.R. Gennaro, Mack Publishing Co.
3. Pharmaceutical Dosage forms: Parenteral, Vol.: I,II, III, Leon Lachman, K.E. Avis, Marcel Dekker inc., NY.
4. Pharmaceutics: The science of dosage form design, Edited by M.E. Aulton. Churchill Livingstone, New York.
5. Indian Pharmacopoeia, Published by Indian Pharmacopoeial Commission, Ghaziabad.
6. Pharmaceutical Production Facilities, Design and Applications: Graham C. Cole, CRC Press In

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Semester-VII

Sterile Products Technology –II (PH420.6)

Credits: 2 (Theory) **Contact Hours per week: 2 (Theory)**

Course Objective :

- To introduce about the routes of administration and the other anatomical aspects for the administration of sterile dosage forms.
- To understand the various approaches for the effective drug delivery through understanding of manufacturing and packaging equipments.
- To make students familiar with various sterile dosage forms and its applications.

Learning Outcomes:

- Students are expected to learn the formulation and quality control aspects of various sterile dosage forms with the specific emphasis on construction and working of equipments.
- Students should understand applications of sterile dosage forms in manufacturing and packaging of drugs/dosage forms.

Outline of course:

No.	Unit	Minimum No. of Contact Hours Approx.	Weightage %
1	Introduction to Sterile dosage forms	08	27
2	Formulation of Sterile dosage forms	12	40
3	Quality Control of Sterile Products	10	33
	Total	**30**	**100%**

Detailed Syllabus

Sr. no.	Unit Details	No. of Hours
1	Introduction to Sterile dosage forms: • Introduction of Parenteral and non-parenteral dosage forms. • Approaches for drug delivery and associated Complications. • Application of sterile dosage forms.	08
2	Formulation of Sterile dosage forms: • Formulation methods, Manufacturing and packaging of Parenterals with focus on equipment for Large volume parenterals (LVP), Small Volume parenterals (SVP), Suspension, Emulsion, Dry powders, Solutions etc. • Formulation methods, manufacturing & packaging of ophthalmic with focus on equipment for Eye drops, ophthalmic suspension, eye lotion, ophthalmic ointments, contact lens solutions etc.	12
3	Quality Control of Sterile Products: Evaluation of sterile products with respect to sterility and Package integrity.	10

Pedagogy:

The course will transact with aim of participation and one to one learning through active classroom interaction, group discussion and presentation mode.

- Classroom teaching :- 15 hrs
- Case study :- 05 hrs
- Group Discussions :- 05 hrs
- Students' Presentations :- 05 hrs

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Recommended Study Materials:

1. The Theory & Practice of industrial pharmacy, Leon Lachman, Lea & Febiger, Varghese Publication House Bombay.
2. Pharmaceutical dosage forms: Parenteral, Vol.: 1, 2, 3, Leon, Lachman, K. E. Avis, Marcel Dekker inc. N.Y.
3. Pharmaceutics: The science of dosage form design, Edited by M.E. Aulton. Churchill Livingstone, New York.
4. Handbook of Pharmaceutical Manufacturing Formulations: Sterile Products, Sarfaraz K. Niazi Volume 6, Informa Healthcare USA, Inc.2009.
5. Parenteral Quality Control: Sterility, Pyrogen, Particulate, and Package Integrity Testing, Michael J. Akers, Daniel S. Larrimore, and Dana Morton Guazz, volume 125.

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SEMESTER - VIII
STERILE PRODUCTS TECHNOLOGY IV (PH426.6)

Credits: 3(Practical) **Contact Hours per week: 3(Practical)**
Credits: 3 (Project) **Contact Hours per week: 3(Project)**

Course Objective:

- To empower students to learn the industrial processes they encounter and to continue to appreciate it through qualification and inculcate in their technical skills.
- To demonstrate technical skills for Sterile Products Manufacturing and training of students for manufacturing of Sterile Preparations on Lab Scale

Learning Outcomes :

- The students are expected to learn formulation and development aspects of various sterile products
- Students expected to understand the concept of Lyophilization and critical parameters to be taken into consideration while developing a freeze drying cycle.

List of Practical:

- To prepare and evaluate 5% dextrose injection.
- To prepare and evaluate 0.5% ciprofloxacin eye drop.
- To demonstrate various aspects of environmental monitoring.
- To demonstrate freeze drying process and freeze drying cycle development.
- To develop freeze drying cycle for 5% Dextrose Solution.
- Freeze drying of Pharmaceutical product: To study the Annealing Phenomena.
- To study the Effect of freezing rate on Pharmaceutical product during Lyophilization process.
- To study the effect of different Lyo-protectant on Pharmaceutical product during Lyophilization process.
- To study the effect of different various concentration of Lyo-protectant on Pharmaceutical product during Lyophilization process.
- To evaluate marketed sterile implant/device product.
- To Design and develop of peptides, proteins & Medical device

Project Guidelines:

Individual /Group projects will be given to the students. The project can be a minor research / field work type, which could be conducted in-house or the students can be deputed for the same in any recognized academic, research or clinical organization.

Sr. No	Work	Hours allotted
1	Discussion with Mentor	10
2	Experimental project /Field work	25
3	Write up, analysis of data and compilation.	10

List of Projects:

- Study of different Lyo-protectant on Pharmaceutical product during Lyophilization process.
- Study of marketed sterile implant/device product.
- Design and development of peptides and proteins
- Design and development of Medical device
- Formulation, evaluation and packaging of parenteral products
- Formulation, evaluation and packaging of ophthalmic products

Recommended Study Materials:

1. The Theory & Practice of industrial pharmacy, Leon Lachman, Lea & Febiger, Varghese Publication House Bombay.
2. Remington's Pharmaceutical Sciences , Edited by A. R. Gennaro, Mack Publishing Co,

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3. Pharmaceutical dosage forms: Parenteral, Vol.: 1, 2, 3, Leon, Lachman, K. E. Avis, Marcel Dekker inc. N.Y.
4. Indian Pharmacopoeia , published by Indian Pharmacopoeial commission, Ghaziabad
5. United State Pharmacopoeia, United State Pharmacopoeial convention INC.
6. British Pharmacopoeia , British Pharmacopoeia commission office, U.K.
7. Handbook of Pharmaceutical Manufacturing Formulations: Sterile Products, Sarfaraz K. Niazi Volume 6, Informa Healthcare USA, Inc.2009.
8. Encyclopedia of Pharmaceutical Technology, Jasmes Swarbrick and James C. Boylan, Marcel Dekker Inc., New York.
9. Achieving Sterility in Medical and Pharmaceutical Products, Nigel A. Halls, volume 64.
10. Development of Biopharmaceutical Parenteral Dosage Forms, edited by John A. Bontempo, volume 85.
11. Parenteral Quality Control: Sterility, Pyrogen, Particulate, and Package Integrity Testing: Third Edition, Revised and Expanded, Michael J. Akers, Daniel S. Larrimore, and Dana Morton Guazz, volume 125.
12. Ophthalmic Drug Delivery Systems: Second Edition, Revised and Expanded, edited by Ashim K. Mitra, volume 130.
13. Injectable Dispersed Systems: Formulation, Processing, and Performance, edited by Diane J. Burgess, volume 149.
14. Environmental Monitoring for Cleanrooms and Controlled Environments, edited by Anne Marie Dixon, volume 164.
15. Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products: Second Edition, Revised and Expanded, edited by Louis Rey and Joan C. May, volume 137.

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