

JSS Academy of Higher Education and Research

JSS College of Pharmacy

Sri Shivarathreshwara Nagara, Mysuru-570015

Ph: 0821-2548353, Fax: 0821-2548359, Email: jsscpsy@jssuni.edu.in

Website: www.jssuni.edu.in

An ISO 9001:2015 Certified Institution



B. Pharm - VI Semester Course Handout 2021-22



Ranked 1st among
the YOUNG
UNIVERSITIES in
Karnataka



JSS College of
Pharmacy,
Mysuru - 9th
Rank in INDIA
2021



INTERNATIONAL
CERTIFICATION
Pharm D Program is
Certified by Accreditation
Council for Pharmacy
Education (ACPE), USA

 JSS ACADEMY OF HIGHER EDUCATION & RESEARCH MYSURU	 2021 NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL A+	 NATIONAL INSTITUTIONAL RANKING FRAMEWORK 34th (University Category)	 ASIAN UNIVERSITY RANKINGS 261-270 31 st in INDIA	 2022 Subject Ranking Clinical & Health 351-400 2 nd in INDIA 93 1 st in INDIA	 ARIAL RANKING OF INSTITUTIONS ON INNOVATION ACHIEVEMENTS 2020 Band A Rank Band 6 to 25
 JSS Medical College - 24 th ★ JSS Dental College & Hospital - 12 th ★ JSS College of Pharmacy, Mysuru - 9 th ★ JSS College of Pharmacy, Ooty - 7 th					



Accredited 'A+' Grade by NAAC

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VISION

To be a leader in pharmaceutical sciences & pharmacy practice education, training, research and continuous professional development for pharmacists and Pharmaceutical Scientists providing competent patient care and nurturing drug discovery and development.

MISSION

- To impart knowledge, develop skills and competencies in students in pharmaceutical sciences and pharmacy practice.
- To Develop and advance the knowledge, attitude and skills of pharmacists and faculty members who can provide comprehensive pharmaceutical care to patients, improve patient outcomes, and meet societal needs for safe and effective drug therapy.
- To develop, promote and nurture research activities in pharmaceutical sciences and pharmacy practice and translating research into healthcare

CORE VALUES

- Innovation, Leadership, Excellence, Integrity, Respect, Professionalism

STRATEGIC PLAN 2020-2025

- JSS Academy of higher Education & Research, College of Pharmacy, will position themselves as the **SMART** Colleges of Pharmacy In the Country by 2025 by developing and advancing

S	Student Quality
M	Motivation
A	Academic Excellence
R	Research & Innovation
T	Technology

Academic Calendar 2021-22 (B.Pharm - VI Semester)

1. Commencement of Classes

B.Pharm – VI Semester

- 23rd February, 2022

2. Sessional Examination Schedule

I	II
Theory - 5 th week of April 2022	Theory - 4 th week of June 2022
Practical - 4 th week of April 2022	Practical – 3 rd week of June 2022

3. Closure of Term

- 1st week of July 2022(Tentative dates)

4. End semester Examination

- 2nd week of July 2022 (Tentative dates)

Teacher's In charge

Class	Class Teacher	Batch No.	Batch Teacher
III B.Pharm VI Semester	Dr. Anand Kumar Tengli	I	Dr. Anand Kumar Tengli
		II	Dr. Dithu thekkekkara
		III	Dr. Asha Spandhana
		IV	Ms. Haripriya

ACTIVITIES AND COORDINATORS 2021-22

Curricular & Co curricular activities

Sl. No	Activities	Coordinator/s
1.	Induction, learning skills and personality development programs for fresher's	DHP/MPG
2.	Selection of class representative in first week of commencement of each course	
3.	Anti ragging cell	HP/ BM
4.	Grievance and redressal cell	MR
5.	Industrial Visits, Training and placements	TS/ABP
6.	Guest lecture & Seminar/ conference/ training / workshop/Webinar <ul style="list-style-type: none"> • organized at college • delivered/attended by staff 	Respective department all HODs/Program coordinators/organizing secretary
7.	Internal Assessment Committee	GVP

	Chairperson Members	RSS/AKT/DAK/BMV
8.	<ul style="list-style-type: none"> Academic Council Board Identification of Advanced/ Medium/ Slow learners 	Class Teachers Subject Teachers
9.	Ethics committee Meeting <ul style="list-style-type: none"> Animal Human 	KLK MR
10.	Time table	DHP TS/ URR/DT/HYK
11.	Internal Quality Assurance Cell Chairperson Members	TMP/HVG / AMM/AKT/RSC/SP/JS
12.	Women's cell (Prevention of Sexual Harassment Cell)	SNM
13.	Scholarship Bureau	RSC/program coordinators/Class teachers
14.	Compilation of publications (Research papers/books/chapters)	BMG
15.	Research Coordination Committee -Compilation of Ph.D details and funded projects - Review of publications	Chairperson – DVG Members – SB/ BRP/JS/JUS
16.	APC (Plagiarism)	Chairperson –TMP Member Secretary-BRP Member-HVG
17.	Pharmacy Education Unit (CCLPE)	MSS/AS
18.	Annual result analysis List of merit students	UG – Subject Teacher, Class teacher & Program committee PG – Course Coordinator & Abhishek (Office)
19.	GPAT and other competitive exams (TOEFL, GRE etc.)	BM/ CSH/MPG/ Class teacher
20.	Library orientation	Librarian
21.	Soft Skills Training	ABP/CIA

Extracurricular activities

Sl. No.	Activities	Coordinator/s
22.	<ul style="list-style-type: none"> Selection of Class Representatives, Pharmaceutical society members Annual planning and execution of Student centered and professional activities including inauguration of IPS 	MSS/ SRD
23.	JASPHARM	BS/ SM / CSH
24.	STUMAG	HYK/ CIA
25.	Sports coordinators	MPV/HKS
26.	NSS coordinators	MPG / UM/ SND

27.	Cultural & Literary coordinators	KNS/ CIA
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Other Institutional activities

Sl. No.	Activities	Coordinator/s
28.	Annual Day celebration / Graduation day	DAT/SM
29.	Course handouts/ Teachers diary/ Student handbook/Faculty handbook	HYK/PS
30.	National Pharmacy Week (NPW) & Pharmacists Day	VJ/ UM + IPA team
31.	Alumni association	HVG/ AKT/SM/BS
32.	Herbal and College Garden	JS/ NPK
33.	ISO	DHP/SNM
34.	Press and publicity	KLK /BMV/OFFICE
35.	Foreign students cell	MPV
36.	Governing council meeting	JUS/ Office
37.	Monthly/Annual report of college activities to JSS AHER and other agencies	HoDs/PG Coordinators/JUS/ST/RSC/AM/ HG, Asha (office)
38.	College website	HKS/BS
39.	Research & Consultancy Co-ordinator • Collaboration with Industries/organizations • Interdepartment/Interdisciplinary research	DVG/ SB/ KM
40.	Coordinator - JSSUonline.com	ABP/TS
41.	JSSU Newsletter	KLK/SRD/ KNS
42.	Annual group photo session	MSS/ SRD
43.	Lab coat and Blazers	JS / Ningaraju
44.	Notice Board (SNB, LNB and IIPC), Departmental staff list	Nagaraju
45.	Stock verification	Office staff /Librarian
46.	Student Liaison	Divya S
47.	Student ID Cards /Attendance entry	Shivanna / Manjunath
48.	Retreat for Pharmacy Students	AKT/ HKS/BRJ
49.	Feedback	VJ
50.	Institute Innovation Cell	HVG/DAK/BM
51.	Practice School	MPG/ST

Program Committee

Sl. No.	Program committees	Chairperson	Member Secretary
52.	D.Pharm	BMV	URR
53.	B.Pharm	GVP	DAT
54.	Pharm.D	MR	RSS
55.	M.Pharm	SNM	AKT

56.	B.Pharm – Practice	MR	BS
57.	PG Diploma	JS	BM

M.Pharm Program Coordinators

Sl. No.	M.Pharm Program	Coordinator
58.	Pharmaceutics	VJ
59.	Industrial Pharmacy	ABP
60.	Pharmaceutical Regulatory Affairs	MPV
61.	Pharmaceutical Quality Assurance	HVG
62.	Pharmaceutical Chemistry	BRP
63.	Pharmaceutical Analysis	AKT
64.	Pharmacology	KLK
65.	Pharmacognosy	NPK
66.	Pharmacy Practice	SP
67.	Pharmaceutical Biotechnology	JS

PG Diploma Program Coordinators

Sl. No.	PG Diploma Program	Coordinator
68.	Pharmacovigilance	CSH
69.	Medicine & Poison Information	RSS
70.	Clinical Research	JUS
71.	Nanotechnology	VJ
72.	Pharmaceutical Quality Assurance	HVG
73.	Pharmaceutical Regulatory Affairs	MPV
74.	Medical Devices	BMV
75.	Intellectual Property Rights	BMV
76.	Computer Aided Drug Design	BRP
77.	Food and Drug Analysis	RSC
78.	Regulatory Toxicology	SB
79.	Phytopharmaceutical and Industrial Applications	NPK

Certificate Course Coordinators

Sl. No.	Certificate Course	Coordinator
80.	Pharmaceutical Quality Assurance	HKS
81.	Herbal Drug Standardization	JS

82.	Medicine Information	RSS
83.	Clinical Research	JUS
84.	Global Regulatory Affairs	MPV

TEACHING STAFF LIST

Sl. No	NAME	QUALIFICATION	DESIGNATION	Department
1.	Dr. T.M. Pramod Kumar (TMP)	M.Pharm., Ph.D.	Professor & Principal	Pharmaceutics
2.	Dr. D. Vishakante Gowda (DVG)	M.Pharm., Ph.D.	Professor & Head	Pharmaceutics
3.	Dr. Balamuralidhara V. (BMV)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
4.	Dr. Gangadharappa H.V. (HVG)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
5.	Dr. M.P. Venkatesh (MPV)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
6.	Dr. Vikas Jain (VJ)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
7.	Dr. Amit B Patil (ABP)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
8.	Dr. Gowrav M P (MPG)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
9.	Mr. Hemanth Kumar S (HKS)	M.Pharm	Asst. Professor	Pharmaceutics
10.	Dr. Riyaz Ali Osmani (RAO)	M.Pharm., Post. Doc.	Asst. Professor	Pharmaceutics
11.	Ms. Asha Spandana K M (ASP)	M.Pharm	Lecturer	Pharmaceutics
12.	Mr B Mahendran (BM)	M.Pharm	Lecturer	Pharmaceutics
13.	Dr. Shailesh T (TS)	M.Pharm., Ph.D.	Lecturer	Pharmaceutics
14.	Ms. Preethi S (PS)	M.Pharm	Lecturer	Pharmaceutics
15.	Dr. M. Ramesh (MR)	M.Pharm., Ph.D.	Professor & Head	Pharmacy Practice
16.	Ms. Shilpa Palaksha (SP)	M.Pharm.	Assoc. Professor	Pharmacy Practice
17.	Dr. Savitha R S (RSS)	M.Pharm.	Assoc. Professor	Pharmacy Practice
18.	Mr. D.H. P. Gowda (DHP)	M.Sc., PGDCA.	Asst. Professor	Pharmacy Practice
19.	Dr. M Umesh (UM)	Pharm D.	Asst. Professor	Pharmacy Practice
20.	Dr. Juny Sebastian (JUS)	M.Pharm., Ph.D.	Asst. Professor	Pharmacy Practice
21.	Dr. Sri Harsha Chalasani (CSH)	M.Pharm., Ph.D.	Asst. Professor	Pharmacy Practice
22.	Dr. Jaidev Kumar B R (BRJ)	M.Pharm.	Lecturer	Pharmacy Practice
23.	Dr. Srikanth M S (MSS)	M.Pharm., Ph.D.	Lecturer	Pharmacy Practice
24.	Mr Balaji S (BS)	M.Pharm	Lecturer	Pharmacy Practice
25.	Dr. U R Rakshith (URR)	Pharm D	Lecturer	Pharmacy Practice
26.	Dr. Acsah Annie Paul (AAP)	Pharm D	Lecturer	Pharmacy Practice
27.	Dr. B.M. Gurupadayya (BMG)	M.Pharm., Ph.D.	Professor	Pharma. Chemistry
28.	Dr. Gurubasavaraj V Pujar (GVP)	M.Pharm., Ph.D.	Professor & Head	Pharma. Chemistry
29.	Dr. R. S. Chandan (RSC)	M.Pharm., Ph.D.	Assoc. Professor	Pharma. Chemistry
30.	Dr. Prashantha Kumar B R (BRP)	M.Pharm., Ph.D.	Assoc. Professor	Pharma. Chemistry

31.	Dr. Anand Kumar Tengli (AKT)	M.Pharm., Ph.D.	Assoc. Professor	Pharma. Chemistry
32.	Dr. Durai Ananda Kumar (DAT)	M.Pharm., Ph.D.	Asst. Professor	Pharma. Chemistry
33.	Dr. H. Yogish Kumar (HYK)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
34.	Dr. Sheshagiri Dixit (SRD)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
35.	Mr. Chetan.I.A (CIA)	M.Pharm	Lecturer	Pharma. Chemistry
36.	Dr. K Mruthunjaya (KM)	M.Pharm., Ph.D.	Professor & Head	Pharmacognosy
37.	Dr. J. Suresh (JS)	M.Pharm., Ph.D.	Professor	Pharmacognosy
38.	Dr. N Paramakrishnan (NPK)	M.Pharm., Ph.D.	Asst. Professor	Pharmacognosy
39.	Mr. Rajaguru A (RG)	M.Pharm.	Lecturer	Pharmaceutical Biotechnology
40.	Ms. Haripriya G (HG)	M Pharm	Lecturer	Pharmacognosy
41.	Dr. S. N. Manjula (SNM)	M.Pharm., Ph.D.	Professor & Head	Pharmacology
42.	Dr. Saravana Babu C (SB)	M.Pharm., Ph.D.	Professor	Pharmacology
43.	Dr. K L Krishna (KLK)	M.Pharm., Ph.D.	Assoc. Professor	Pharmacology
44.	Ms. A M Mahalakshmi (AMM)	M.Pharm.	Asst. Professor	Pharmacology
45.	Ms. Seema Mehdi (SM)	M.Pharm	Lecturer	Pharmacology
46.	Dr. Nagashree K S (KNS)	M.Pharm., Ph.D	Lecturer	Pharmacology
47.	Dr. Dithu Thekkekkara (DT)	M.Pharm., Ph.D	Lecturer	Pharmacology

B.PHARM

Program Educational Objectives (PEOs):

PEO 1: To acquire the theoretical knowledge of pharmaceutical sciences

PEO 2: To acquire practical skills in

- isolation of medicinal compounds from natural sources
- synthesis and analysis of medicinal compounds
- screening medicinal compounds for pharmacological activities
- formulation of pharmaceutical dosage forms and their evaluation

PEO 3: To develop competent Pharmacists with ethical attitude, research intuition, leadership qualities, to participate in public health programs and engage in life-long learning

Program Outcomes (POs):

1. Ability to acquire knowledge of pharmaceutical sciences
2. Ability to design and conduct experiments, to analyze and interpret data
3. Ability to demonstrate effective planning, develop and implement plans within time frame.

4. Ability to function effectively individually and on teams, including diverse and multidisciplinary, to accomplish a task.
5. Ability to understand and appreciate the role of pharmacist in healthcare services.
6. Understanding of professional, ethical, legal, security and social issues and responsibilities.
7. Ability to understand contemporary issues relating to pharmacy profession and challenges ahead.
8. Awareness of ethical and professional responsibilities.
9. Possess the necessary interpersonal and communication skills to be a productive member of the team in work environment.
10. Ability to use current techniques, skills, and modern tools.
11. A strong background and motivation to pursue life-long learning

COURSE HAND OUT 2021-22

Class: VI Semester - B. Pharm

1. Course Details

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry – III (Theory)	3	1	4
BP602T	Pharmacology-III (Theory)	3	1	4
BP603T	Herbal Drug Technology (Theory)	3	1	4
BP604T	Biopharmaceutics And Pharmacokinetics (Theory)	3	1	4
BP605T	Pharmaceutical Biotechnology (Theory)	3	1	4
BP606P	Medicinal Chemistry – I (Practical)	4	-	2
BP607P	Medicinal Chemistry- III (Practical)	4	-	2
BP608P	Pharmacology-III (Practical)	4	-	2
BP609P	Herbal Drug Technology (Practical)	4	-	2
Total		31	5	28

2. Evaluation:

a. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment, as per the scheme given below.

Table 1: Scheme for awarding internal assessment: Continuous mode

THEORY		
Criteria	Maximum Marks	
Attendance	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
<i>Total</i>	10	5
PRACTICALS		
Attendance	2	
Based on Practical Records, Regular viva voce, etc.	3	
<i>Total</i>	5	

Table 2: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

b. Sessional Exams

1. Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements.
2. Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Multiple Choice Questions (MCQs) (Answer all the questions)	=	10 x 1 = 10
I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 2 out of 3)	=	2 x 5 = 10

Total = 30 marks

For subjects having Non University Examination

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10

II. Short Answers (Answer 4 out of 6) = 4 x 5 = 20

Total = 30 marks

Question paper pattern for practical sessional examinations

I. Synopsis = 10

II. Experiments = 25

III. Viva voce = 05

Total = 40 marks

3. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to VIII shall be conducted by the university except for the subjects notified as non-university examinations

Table 3: Scheme for internal assessments and university examination - Semester-VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Course code	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3Hrs	100
BP606T	Quality Assurance – Theory	10	15	1 Hr	25	75	3Hrs	100

BP607P	Medicinal chemistry III – Practical	5	10	1 Hr	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	1 Hr	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	1 Hr	15	35	4 Hrs	50
Total		75	120	18 Hrs	195	555	30 Hrs	750

* The lateral entry students must undertake non-university Examination for Communication skills and computer applications in pharmacy subjects

4. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of B.Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

5. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified (in promotion and award of grades), then he/she shall reappear for the university examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

6. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the Internal assessment. The re-conduct of the sessional exam should be completed before the commencement of next semester theory examinations.

7. Re-examination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 3. The exact dates of examinations will be notified from time to time.

Table 4: Tentative schedule of university examinations and supplementary examinations

Semester	Regular examinations	Supplementary examinations
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

Question pattern for university theory examinations for 75 marks paper

I. Multiple Choice Questions (MCQs)

$$\begin{aligned} \text{(Answer all the questions)} &= 20 \times 1 = 20 \\ \text{I. Long Answers (2 out of 3)} &= 2 \times 10 = 20 \\ \text{II. Short Answers (7 out of 9)} &= 7 \times 5 = 35 \end{aligned}$$

$$\text{Total} = \text{75 marks}$$

Question pattern for university theory examinations for 50 marks paper

$$\begin{aligned} \text{I. Long Answers (2 out of 3)} &= 2 \times 10 = 20 \\ \text{II. Short Answers (6 out of 8)} &= 6 \times 5 = 30 \end{aligned}$$

$$\text{Total} = \text{50 marks}$$

8. Grading of performances

Letter grades and grade points allocations

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.

Table 5: Letter grades and grade points equivalent to percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	A+	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent in any form of evaluation/examination, letter grade allocated to him/her should be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

9. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

$$\begin{aligned} \text{First Class with Distinction} &= \text{CGPA of 7.50 and above} \\ \text{First Class} &= \text{CGPA of 6.00 to 7.49} \\ \text{Second Class} &= \text{CGPA of 5.00 to 5.99} \end{aligned}$$

10. Attendance: The marks is allotted based on the attendance percentage (Table 2)

11. Chamber consultation hours: Any time during college hours.

12. Tutorial Class: Objective of the tutorial is to enhance the learning ability and help students in better understanding of the subject. This provides a best opportunity for the students to clarify their

subject doubts. This involves discussions, presentations on specified topics, assignments and evaluation.

BP601T. MEDICINAL CHEMISTRY – III (Theory)**Teacher/s: Dr. Anand Kumar Tengli****45 Hours (3 Hours/ week)**

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

Lecture wise program

Chapter No.	Title	No. of Hours
1	Antibiotics Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.	5
2	β-Lactam antibiotics: Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams Aminoglycosides: Streptomycin, Neomycin, Kanamycin	5

	Tetracyclines: Tetracycline,Oxytetracycline,Chlortetracycline,Minocycline, Doxycycline	
3	Antibiotics Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. Macrolide: Erythromycin Clarithromycin, Azithromycin. Miscellaneous: Chloramphenicol*, Clindamycin.	5
4	Prodrugs: Basic concepts and application of prodrugs design. Antimalarials: Etiology of malaria. Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil. Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovoquone	5
5	Anti-tubercular Agents Synthetic anti tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.	5
6	Urinary tract anti-infective agents Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine. Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir,	5

	Ritonavir.	
7	<p>Antifungal agents:</p> <p>Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.</p> <p>Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.</p> <p>Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.</p> <p>Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.</p>	4
8	<p>Sulphonamides and Sulfones</p> <p>Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.</p> <p>Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.</p> <p>Sulfones: Dapsone*.</p>	4
9	<p>Introduction to Drug Design</p> <p>Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques.</p>	5
10	<p>Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis. of combinatorial.</p>	2

Theory Internal assessment syllabus

Internal assessment No.	Syllabus
	Chapters no.
I	1 to 5
II	6 to 10

BP607P. MEDICINAL CHEMISTRY- III (Practical)**Teacher/s: Dr. Anand Kumar Tengli****60 Hours (4 hours / week)**

I	Preparation of drugs and intermediates 1 Sulphanilamide 2 7-Hydroxy, 4-methyl coumarin 3 Chlorobutanol 4 Triphenyl imidazole 5 Tolbutamide 6 Hexamine
II	Assay of drugs 1 Isonicotinic acid hydrazide 2 Chloroquine 3 Metronidazole 4 Dapsone 5 Chlorpheniramine maleate 6 Benzyl penicillin
III	Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
	Drawing structures and reactions using chem draw®
	Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.

5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP602 T. PHARMACOLOGY-III (Theory)**Teacher/s: Dr. Dithu Thekkekkara****45 Hours (3 Hours/ week)**

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chrono pharmacology.

Objectives: Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisonings and
3. appreciate correlation of pharmacology with related medical sciences

Course Content:

Lecture wise program

Chapter No.	Title	No. of Hours
1	Pharmacology of drugs acting on Respiratory system a. Anti -asthmatic drugs b. Drugs used in the management of COPD	5
2	c. Expectorants and antitussives d. Nasal decongestants e. Respiratory stimulants	5
3	Pharmacology of drugs acting on the Gastrointestinal Tract a. Antiulcer agents. b. Drugs for constipation and diarrhoea.	5
4	c. Appetite stimulants and suppressants. d. Digestants and carminatives. e. Emetics and anti-emetics.	5
5	Chemotherapy a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole.	5

6	c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides	5
7	Chemotherapy I. Urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy.	4
8	Immunopharmacology a. Immunostimulants b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars	4
9	Principles of toxicology a. Definition and basic knowledge of acute, subacute and chronic toxicity. b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity c. General principles of treatment of poisoning d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.	4
10	Chronopharmacology a. Definition of rhythm and cycles. b. Biological clock and their significance leading to chronotherapy.	3

Theory Internal assessment syllabus

Internal assessment No.	Syllabus
	Chapters no.
I	1 to 5
II	6 to 10

BP 608 P. PHARMACOLOGY-III (Practical)

Teacher/s: Dr. Dithu Thekkekkara

60 Hours (4 Hrs/ week)

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine

8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams &Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

Teacher/s: Ms. Haripriya G

45 Hours (3 Hrs/ week)

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP.

Course Content:

Lecture wise program

Chapter No.	Title	No. of Hours
1	Herbs as raw materials: Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material	6
2	Biodynamic Agriculture: Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides. Indian Systems of Medicine a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.	5

3	<p>Nutraceuticals: General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina.</p>	4
4	<p>Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.</p>	3
5	<p>Herbal Cosmetics : Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.</p> <p>Herbal excipients: Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.</p>	5
6	<p>Herbal formulations : Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes.</p>	5
7	<p>Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs, Stability testing of herbal drugs.</p> <p>Patenting and Regulatory requirements of natural products:</p> <p>a) Definition of the terms: Patent, IPR, Farmers right, Breeder’s right, Bioprospecting and Biopiracy</p> <p>b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.</p>	5
8	<p>Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.</p>	5
9	<p>General Introduction to Herbal Industry</p> <p>Herbal drugs industry: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.</p>	4

10	Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.	3
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Theory Internal assessment syllabus

Internal assessment No.	Syllabus Chapters no.
I	1 to 5
II	6 to 10

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

Teacher/s: Teacher/s: Ms. Haripriya G

60 Hours (4 hrs / week)

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS(Theory)

Teacher/s: Mrs. Asha Spadana

45 Hours (3 Hrs/ week)

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

Objectives: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

Lecture wise program

Chapter No.	Title	No. of Hours
1	Introduction Biopharmaceutics to Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes	5
2	Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	5
3	Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs.	5
4	Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, <i>in-vitro</i> drug dissolution models, <i>in-vitro-in-vivo</i> correlations,	5

	bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.	
5	Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations.	5
6	Pharmacokinetics parameters - KE , $t_{1/2}$, V_d , AUC , K_a , Cl_t and CLR - definitions methods of eliminations, understanding of their significance and Application.	5
7	Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing.	4
8	Steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.	4
9	Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.	4
10	c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.	3

Theory Internal assessment syllabus

Internal assessment No.	Syllabus
	Chapters no.
I	1 to 5
II	6 to 10

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.

6. Hand Book of Clinical Pharmacokinetics, ByMilo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: ByMalcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvania

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

Teacher/s: Mr. Rajaguru A

45 Hours (3 Hours/ week)

Scope: Biotechnology has a long promise to revolutionize the biological sciences and technology. Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting. Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs. Biotechnology has already produced transgenic crops and animals and the future promises lot more. It is basically a research-based subject.

Objectives: Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Course Content:

Lecture wise program

Chapter No.	Title	No. of Hours
1	a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. b) Enzyme Biotechnology- Methods of enzyme immobilization and applications. c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.	5
2	d) Brief introduction to Protein Engineering. e) Use of microbes in industry. Production of Enzymes- General consideration -Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. f) Basic principles of genetic engineering.	5
3	a) Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in medicine.	5

4	c) Application of r DNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. d) Brief introduction to PCR.	5
5	Types of immunity- humoral immunity, cellular immunity a) Structure of Immunoglobulins b) Structure and Function of MHC c) Hypersensitivity reactions, Immune stimulation and Immune suppressions. d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.	5
6	e) Storage conditions and stability of official vaccines f) Hybridoma technology- Production, Purification and Applications g) Blood products and Plasma Substitutes.	5
7	a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting. b) Genetic organization of Eukaryotes and Prokaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.	4
8	d) Introduction to Microbial biotransformation and applications. e) Mutation: Types of mutation/mutants.	4
9	a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,	4
10	d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.	3

Theory Internal assessment syllabus

Internal assessment No.	Syllabus
	Chapters no.
I	1 to 5
II	6 to 10

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.

2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory) 45 Hours

Teacher/s: Dr. Gowrav M P

45 Hours (3 Hrs/ week)

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

Objectives: Upon completion of the course student shall be able to:

- understand the cGMP aspects in a pharmaceutical industry
- appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceutical industries
- understand the responsibilities of QA & QC departments

Course Content:

Lecture wise program

Chapter No.	Title	No. of Hours
1	Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP Total Quality Management (TQM): Definition, elements, philosophies. ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines.	5
2	Quality by design (QbD): Definition, overview, elements of QbD program, tools, ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation : Principles and procedures	5
3	Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.	5
4	Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	5

5	Quality Control: Quality control test for containers, rubber closures and secondary packing materials. Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation.	5
6	Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.	5
7	Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.	4
8	Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.	4
9	Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.	4
10	Warehousing: Good warehousing practice, materials management.	3

Theory Internal assessment syllabus

Internal assessment No.	Syllabus
	Chapters no.
I	1 to 5
II	6 to 10

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

JSS Academy of Higher Education & Research
JSS College of Pharmacy
 Sri ShivarathreeshwaraNagara, Mysore-570015
 CLASSTIME TABLE – 2021-22

Class: B. PHARM (Semester- VI)

Lunch Break: 1.00 to 2.00 PM
Tea Break: 10.40 to 11.10 AM
3.50 PM to 4.05 PM

Time Day	9.00-9.50AM	9.50-10.40AM	11.10-12.05PM	12.05-1.00PM	2.00-2.55PM	2.55-3.50PM	4.05-5.00PM	5.00-5.55PM	
Monday	-----	P. Col-III DITTU	QA(Tu) MPG	QA MPG LH4	P. Col-III DITTU (LH4)	Pharma. Biotech RG	Pharma. Biotech RG	-----	
Tuesday	-----	BP&PK ASP	MC-III AKT	BP&PK ASP	←- Medicinal Chem-III ----- ←- Pharmacology-III----- ←- Herbal Drug Tech-----	LUNCH BREAK	←- Batch - I --AKT-----→ ←- Batch - II ----DITHU----→ ←- Batch - III--HP-----→	TEA BREAK	
Wednesday	-----	HERBAL DRUG TECH HP	MC-III AKT	HERBAL DRUG TECH HP	←- Medicinal Chem-III ----- ←- Pharmacology-III----- ←- Herbal Drug Tech-----		←- Batch - II --AKT-----→ ←- Batch - III ----TOSIF----→ ←- Batch - IV--HP-----→		
Thursday	HERBAL DRUG TECH HP	MC-III AKT	P. Col-III(LH2) DITTU	QA MPG	←- Medicinal Chem-III ----- ←- Pharmacology-III----- ←- Herbal Drug Tech-----		←- Batch - III --ARUN-----→ ←- Batch - IV----DITHU----→ ←- Batch - I--HP-----→		
Friday	MC-III(Tu) AKT	Pharma. Biotech RG	P. Col-III(Tu)(LH2) DITTU	HERBAL DRUG TECH(Tu) HP	←- Medicinal Chem-III ----- ←- Pharmacology-III----- ←- Herbal Drug Tech-----		←- Batch - IV --AKT-----→ ←- Batch - I ----SAH-----→ ←- Batch - II--HP-----→		
Saturday	QA MPG	BP&PK ASP	Pharma. Biotech (TU) RG-LH4	BP&PK(TU) ASP	-----				

*Effective from: March 21st - 2022

Note: 1. No tea break for practical's

Time table Coordinator
 Copy: SNB/LNB/SCF/e-copy-Teachers/ Office incharge-Time table / Time table Coordinator

Principal

OPC8.1SOP(2)F(1)