

JSS Academy of Higher Education and Research

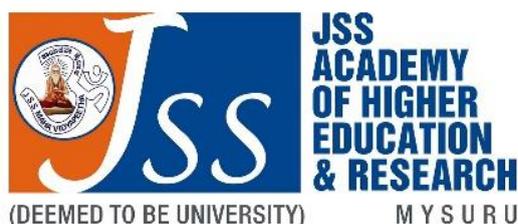
JSS College of Pharmacy

Sri Shivarathreswara Nagara, Mysuru-570015

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An ISO 9001:2015 Certified Institution



Vth Pharm.D. Course Handout 2023-24

 A+ NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL	 34th NATIONAL INSTITUTIONAL RANKINGS FRAMEWORK 2023 University Category	 351-400 2 nd in INDIA Subject Ranking - Clinical & Health 126-150	 301-350 QS ASIA RANKING Southern Asia 65	 101-150 Pharmacy & Pharmacology Medicine 651-680	 301-400 Impact Ranking SDG-3 Good Health & Well-being 16 th Globally 1 st in INDIA	 1st in the Asia Pacific QS I-GAUGE Advanced E-Learning Excellence for Academic Digitisation (E-LEAD) ACPE certified Pharm.D Program	 1st in the Asia Pacific ACPE certified Pharm.D Program
 2023 JSS Medical College - 37 th * JSS Dental College & Hospital - 11 th * JSS College of Pharmacy, Mysuru - 7 th * JSS College of Pharmacy, Ooty - 4 th							

Academic Calendar 2023-24 (V Pharm.D.)

Tentative Dates of Examinations

I Sessional Examinations for II to V Pharm D & I Pharm D	6 th September 2023 & 23 rd September 2023
II Sessional Examinations for I to V Pharm D	18 th Dec 2023
III Sessional Examinations for I to V Pharm D	18 th March 2024
University Examination	1 st April 2024

Teacher's Incharge

Class	Class Teacher	Batch No.	Batch Teacher
V Pharm.D.	Dr. B R Jaidev (BRJ)	I	Dr. B R Jaidev
		II	Dr. Savitha R S

CURRICULAR & CO-CURRICULAR ACTIVITIES & COORDINATORS FOR THE ACADEMIC YEAR 2023-24

Sl. No	Activities	Coordinator/s	Tentative schedule of meeting/activity
1.	Induction, learning skills, and personality development programs for freshers' day	Coordinator: AKT Members: BRJ, DT	July/August 2023
2.	Anti-ragging cell	Coordinators: JS, KSN, & Committee members	July/August 2023
3.	Grievance and redressal cell	Coordinator: GVP & Committee members	Meetings - twice/year
4.	Gender Sensitization Committee	Coordinator: SNM & Committee members	Meetings - twice/year
5.	Industrial Visits, Training, and placements	Coordinator: ABP Members: MGS, SM, SD, LR, UM	September 2023- June 2024

6.	Internal Quality Assurance Cell (IQAC) Team	Chairman- GVP Coordinator- HVG Member Secretary: SP Members: RSC, MPV, KSN, CIA, HP	4 meetings/year
7.	Guest lecture & Seminar/ Conference/ Training / Workshop/Webinar organized at college / delivered/ attended by staff- Validation of college data.	IQAC Team	Throughout the academic year
8.	Governing council meeting	GVP + IQAC Team AAO & Asha B	July 2023 and Feb 2024
9.	Preparation of documents and submission for NIRF, NAAC, NBA, PCI or any other agency	Team IQAC	<ul style="list-style-type: none"> • Throughout the academic year
10.	Internal Assessment Committee (IAC)	Coordinator: GVP Members: All program Coordinators (M Pharm, B. Pharm, D Pharm, Pharm D)	Meetings - twice/year Schedule as per the academic calendar
11.	ACPE committee- Interim report and others	Coordinator: MR /RSS Member: SP & UM	<ul style="list-style-type: none"> • As required
12.	Academic Council Board (ACB) <ul style="list-style-type: none"> • Student Progression (Advanced/ Medium/ Slow learners) • Mentors Diary- Student profile 	Class teachers and Program Coordinators	<ul style="list-style-type: none"> • After each sessional exam • Regular monitoring of Mentee

13.	Ethics committee	<ul style="list-style-type: none"> IAEC-SBC IEC-CSH 	<ul style="list-style-type: none"> Twice a year
14.	Class Timetable committee	Coordinator: VJ Member: BRP, NPK, URR, DT	<ul style="list-style-type: none"> Twice a year (June & Nov 2023)
15.	Women's cell/Prevention of Sexual Harassment Cell/Internal Complaints committee (ICC)	SNM & committee members	<ul style="list-style-type: none"> Meetings twice a year (June & Nov 2023)
16.	Scholarship Bureau	Coordinator: RSC Member: SRD	Soon after the announcement of the Scholarships
17.	Compilation of publications (Research papers/ books/chapters)	Coordinator: SRD	1st of Every month
18.	Research Coordination & Consultancy Committee Compilation of Ph.D. details and funded projects Review of publications Collaboration with Industries/organizations Interdepartmental/ Interdisciplinary research	Chairman-SBC Members-All HoDs	At least 3 meetings/year
19.	Department Academic Integrity Panel (DAIP) - Plagiarism Check for PhD & M Pharm thesis	Chairman-TMP Member Secretary: BRP Member-VJ	During the submission of thesis by the students
20.	Pharmacy Education Unit – for CCLPE activities	MSS	At least 5 activities/ year
21.	Annual result analysis and List of merit students	Class teachers and M Pharm Course Coordinators	Soon after the exam results
22.	GPAT and other competitive exams (TOEFL, GRE etc.)	Coordinator: SNM Members: RAO, RJ	Planning of coaching Throughout the academic year
23.	Library orientation	Librarian	July/August 2023
24.	Library staff coordinator	Coordinator: HYK Members: PP, AAR, RG, DT, and AAP	Two meetings/year Yearly textbook requirements
25.	Soft Skills Training	Coordinator: ABP Member: MGS	At least 3 activities/year
26.	International Student Rotation	CSH	As and when
27.	Hackathon	RAO	At least two events/ year

28.	Golden Jubilee-Souvenir, press and publicity	Chairman- TMP/ GVP Members-BS, KSN, RJ, RG, CIA	August 2022- August 2023
29.	SDG- Activities and Compendium	CIA, PP	<ul style="list-style-type: none"> • Compendium- August 23 • Regular activity under each SDG
30.	Course handouts/ Teachers' diary/ Student Handbook/Faculty Handbook.	NPK & HYK	<ul style="list-style-type: none"> • July/ August 2023
31.	National Pharmacy Week (NPW) & Pharmacists Day	Coordinator: UM & IPA office bearers	<ul style="list-style-type: none"> • Nov-Dec 2023
32.	Alumni association	Coordinator: HVG Member: SM	<ul style="list-style-type: none"> • August/September 2023
33.	Herbal and College Garden	NPK	<ul style="list-style-type: none"> • Regular monitoring
34.	ISO 9001:2015	Coordinator: SNM Member: SM	<ul style="list-style-type: none"> • 2 Internal audits (July and December) • Surveillance/ Recertification audit
35.	Press and publicity	Coordinator: BRP Member: TS	During the Conferences/ workshop organized
36.	Foreign students' cell	MPV	At least 2 meetings
37.	Monthly/Annual report of college and JSSU Newsletter & Annual report of JSS AHER and other agencies	Coordinator: KM Members: PP, HP, AAP, DT, AAR	Monthly report
38.	College website updating	Coordinator: HKS Members: AKT, DT, RG, URR, MGS	Throughout the year
39.	JSSUonline.com Student promotion, Timetable, teacher allotment, and others	Coordinator - SRD	Throughout the year
40.	Annual group photo session	HP, RG	Feb 2024
41.	Lab coat and Blazers	JS and Ningaraju	August/Sep 2023
42.	Notice Board (SNB, LNB, and IIPC), Departmental staff list	Shadakshari	Throughout the year
43.	Stock verification	Ningaraju	April/May 2024
44.	Student Liaison	Coordinator: AAO Member: TS	Throughout the year
45.	Student ID Cards /Attendance entry	Shivanna & Kumar	Aug/Sep 2023
46.	Retreat for Pharmacy Students	AKT	Nov/Dec 2023
47.	Retreat for Teachers	JS	November 2023/May 2024

48.	Feedback	VJ & SA	April/May 2023
49.	Institute Innovation Cell	Coordinator: RAO Member: DT	Throughout the year
50.	Practice School	Coordinator: ST Member: KSN, PS, MSS, PP	Throughout the year
51.	MOUs-Collate College initiation activities	HP	June 2023 & Jan 2024
Extracurricular activities			
Sl. No.	Activities	Coordinator/s	Tentative schedule of meeting/activity
52.	Selection of Class Representatives, Pharmaceutical society members Annual planning and execution of Student-centered and professional activities including the inauguration of IPS	Coordinator: MPV Member: MSS	July 2023
53.	JASPHARM- College magazine	Coordinator: BS Member: AAP	July 2024
54.	STUMAG- College wall magazine	TSK, LR	At least 3 issues/year
55.	Sports coordinators	HYK, SND	Feb 2024
56.	NSS coordinators	Program Officer- URR Assistant PO - SND	Regular activities and special camp
57.	Cultural & Literary coordinators	PS, MGS, LR	Nov 2023
58.	Annual Day Celebration & Graduation Day	CIA, ASP	March 2024, July 2024
59.	Foreign languages	CIA, PP	Throughout the year
60.	College Calendar & Events	RSC, MPV	June / July 2023

Program Committee			
Sl. No.	Program committees	Chairperson	Member Secretary
61.	D. Pharm	GVP	MSS
62.	B. Pharm	GVP	MPV
63.	Pharm. D	TMP	CSH
64.	M. Pharm	TMP	RSC
65.	Diploma programs	GVP	RJ
Sl. No.	M. Pharm Program		Coordinator

66.	Pharmaceutics	RAO
67.	Industrial Pharmacy	ASP
68.	Pharmaceutical Regulatory Affairs	MPV
69.	Pharmaceutical Quality Assurance	HKS
70.	Pharmaceutical Chemistry	HYK
71.	Pharmaceutical Analysis	AKT
72.	Pharmacology	SM
73.	Pharmacognosy	NPK
74.	Pharmacy Practice	UM
75.	Pharmaceutical Biotechnology	RG
Sl. No.	PG Diploma Program	Coordinator
76.	Pharmacovigilance	CSH
77.	Medicine & Poison Information	UM
78.	Clinical Research	SP
79.	Pharmaceutical Quality Assurance	TS
80.	Pharmaceutical Regulatory Affairs	MPV
81.	Medical Devices	MGS
82.	Intellectual Property Rights	ARR/ HYK
83.	Computer-Aided Drug Design	SD
84.	Food and Drug Analysis	RJ
85.	Regulatory Toxicology	SBC
86.	Phytopharmaceutical and Industrial Applications	NPK
87.	Quality control	AKT
Sl. No.	Certificate Course	Coordinator
88.	Pharmaceutical Quality Assurance	HKS
89.	Herbal Drug Standardization	HP

90.	Medicine Information	BRJ
91.	Clinical Research	SP
92.	Global Regulatory Affairs	MPV
93.	Food & Nutraceuticals	RJ
94.	Telemedicine	BRJ

TEACHING STAFF LIST 2023-24

Sl. No	NAME	QUALIFICATION	DESIGNATION	DEPARTMENT
1.	Dr. T.M. Pramod Kumar (TMP)	M.Pharm., Ph.D.	Professor & Principal	Pharmaceutics
2.	Dr. Gurubasavaraj V Pujar (GVP)	M.Pharm., Ph.D.	Professor & Vice Principal	Pharma. Chemistry
3.	Dr. Balamuralidhara V. (BMV)	M.Pharm., Ph.D.	Assoc. Professor & Head	Pharmaceutics
4.	Dr.K. Bangarurajan (KBR)	M.Pharm., Ph.D.	Professor	Pharmaceutics
5.	Dr. Gangadharappa H.V. (HVG)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
6.	Dr. M.P. Venkatesh (MPV)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
7.	Dr. Vikas Jain (VJ)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
8.	Dr. Amit B Patil (ABP)	M.Pharm., Ph.D.	Assoc. Professor	Pharmaceutics
9.	Dr. Hemanth Kumar S (HKS)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
10.	Dr. Osmani Mir Riyaz Ali MahafezAli (RAO)	M.Pharm., Ph.D.	Asst. Professor	Pharmaceutics
11.	Dr. Asha Spandana K M (ASP)	M.Pharm., Ph.D.	Lecturer	Pharmaceutics
12.	Dr. Shailesh T(TS)	M.Pharm., Ph.D.	Lecturer	Pharmaceutics
13.	Ms. Preethi S (PS)	M.Pharm	Lecturer	Pharmaceutics
14.	Ms. Akhila AR (AAR)	M.Pharm	Lecturer	Pharmaceutics
15.	Mr. Trideva Sastri K (TSK)	M.Pharm	Lecturer	Pharmaceutics
16.	Dr.Meghana G S(MGS)	M.Pharm., Ph.D.	Lecturer	Pharmaceutics
17.	Dr. Savitha R S (RSS)	M.Pharm.	Assoc. Professor & Head	Pharmacy Practice
18.	Dr. M. Ramesh (MR)	M.Pharm., Ph.D.	Professor	Pharmacy Practice
19.	Ms. Shilpa Palaksha (SP)	M.Pharm.	Assoc. Professor	Pharmacy Practice
20.	Mr. D.H. P. Gowda (DHP)	M.Sc., PGDCA.	Asst. Professor	Pharmacy Practice
21.	Dr. M Umesh (UM)	Pharm D.	Asst. Professor	Pharmacy Practice
22.	Dr. Sri Harsha Chalasani (CSH)	M.Pharm., Ph.D.	Asst. Professor	Pharmacy Practice
23.	Dr. Jaidev Kumar B R (BRJ)	M.Pharm.	Lecturer	Pharmacy Practice
24.	Dr. Srikanth M S (MSS)	M.Pharm., Ph.D.	Lecturer	Pharmacy Practice
25.	Mr Balaji S (BS)	M.Pharm	Lecturer	Pharmacy Practice
26.	Dr. U R Rakshith (URR)	Pharm D	Lecturer	Pharmacy Practice
27.	Dr. Acsah Annie Paul (AAP)	Pharm D	Lecturer	Pharmacy Practice

28.	Dr Siddartha N Durappanavar (SND)	Pharm D	Resident	Pharmacy Practice
29.	Dr. B.M. Gurupadayya (BMG)	M.Pharm., Ph.D.	Professor & Head	Pharma. Chemistry
30.	Dr. R. S. Chandan (RSC)	M.Pharm., Ph.D.	Assoc. Professor	Pharma. Chemistry
31.	Dr. Prashantha Kumar B R (BRP)	M.Pharm., Ph.D.	Assoc. Professor	Pharma. Chemistry
32.	Dr. Anand Kumar Tengli (AKT)	M.Pharm., Ph.D.	Assoc. Professor	Pharma. Chemistry
33.	Dr. H. Yogish Kumar (HYK)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
34.	Dr. Sheshagiri Dixit (SD)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
35.	Dr Rupshee Jain (RJ)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
36.	Mr. Chetan.IA(CIA)	M.Pharm	Lecturer	Pharma. Chemistry
37.	Dr. Prabitha P (PP)	M.Pharm., Ph.D.	Lecturer	Pharma. Chemistry
38.	Dr. J. Suresh (JS)	M.Pharm., Ph.D.	Professor & Head	Pharmacognosy
39.	Dr. K Mruthunjaya (KM)	M.Pharm., Ph.D.	Professor	Pharmacognosy
40.	Dr. N Paramakrishnan (NPK)	M.Pharm., Ph.D.	Asst. Professor	Pharmacognosy
41.	Ms. Haripriya G (HG)	M Pharm	Lecturer	Pharmacognosy
42.	Dr. Logesh R (LR)	M.Pharm., Ph.D.	Lecturer	Pharmacognosy
43.	Mr. Rajaguru A (RG)	M.Pharm	Lecturer	Pharmaceutical Biotechnology
44.	Mr. Siva Armugam (SA)	M.Pharm	Lecturer	Pharmaceutical Biotechnology
45.	Dr. K L Krishna (KLK)	M.Pharm., Ph.D.	Assoc. Professor & Head	Pharmacology
46.	Dr. S. N. Manjula (SNM)	M.Pharm., Ph.D.	Professor	Pharmacology
47.	Dr. Saravana Babu C (SB)	M.Pharm., Ph.D.	Professor	Pharmacology
48.	Dr. Seema Mehdi (SM)	M.Pharm., Ph.D.	Lecturer	Pharmacology
49.	Dr. Nagashree K S (KSN)	M.Pharm., Ph.D	Lecturer	Pharmacology
50.	Dr. Dithu Thekkekkara (DT)	M.Pharm., Ph.D	Lecturer	Pharmalogy

PHARM D

Program outcomes:

Outcome 1 - Development of patient centered knowledge and skills: The student should understand and possess the knowledge and skills required to demonstrate the ability to provide patient centered pharmaceutical care services.

Outcome 2 - Development of pharmaceutical care plan: The student should be able to formulate a pharmaceutical care plan by working in close relation with healthcare professionals, and patient/care taker in order to ensure the enhanced therapeutic outcome in the patient. Also, the pharmaceutical care plan includes maximization of therapeutic benefit by detecting, preventing and resolving drug related problems. The student should be able to recommend pharmaceutical care plan based on evidence, and follow-up and document the outcomes of the pharmaceutical care service.

Outcome 3 – Hospital and community pharmacy management: The student should be able to accurately interpret prescriptions, dispense medications and manage drug distribution system adhering to patient needs, in compliance with policies and guidelines of the hospital pharmacy, good community pharmacy practice and the recommendations of regulatory agencies. Also able to prepare inventory, procure, and use appropriate methods of drug storage and adopt appropriate techniques of drug distribution to ensure correct dispensing of medicines.

Outcome 4 – Promote public healthcare program: The student should be able to participate in various public health care programs of the nation including disease prevention initiatives to improve public health. Contribute to the development and promotion of national health policies including rational drug use program and essential drug policy.

Outcome 5 – Ethics and professional integrity: The student should deliver the duties in accordance with legal, ethical, social, economic, and professional guidelines with integrity. Able to provide patient care services by making rational and ethical decisions that represent the best interest of the patient and the society, and respect the patient, healthcare professionals, and the privacy and confidentiality of health information.

Outcome 6 - Analytical, critical and decision making skills: The student should be able to retrieve, understand, interpret, apply, analyze, synthesize, and evaluate information. Able to apply critical thinking and interpretational skills to identify, manage, and prevent problems and make appropriate decisions.

Outcome 7 - Communication skills: The student should be able to communicate effectively with patients/caretakers, healthcare professionals. Able to effectively counsel, provide medicines information, and educate patients, caretakers & healthcare professionals about medication therapy and other health related issues. Effective communication includes use of both oral and written communications skills and various communication techniques.

Outcome 8 - Leadership and entrepreneurship skills: The student should be able to achieve leadership skills through team work and by involving in organizing various community outreach programs with sound decision making skills. Also the student should enhance the entrepreneurial skills by finding or creating new prospects in challenging professional environments.

Outcome 9 - Interprofessional collaborative practice: Student should be able to identify unique opportunities for professional collaboration towards patient-centered pharmaceutical care services and demonstrate the ability to interact and work with multidisciplinary healthcare teams.

Outcome 10 - Design and conduct of need based research: The student should be able to understand the research needs of the region/nation, and design and conduct the research that would add value to the healthcare requirements of the patients and community/society.

Outcome 11 - Digital literacy: Students should be able to use computers and gadgets to search, retrieve, analyze, store, create, present and exchange information, and interact and participate in interactive networks through the Internet or through any other digital platform to enrich pharmaceutical care services.

Outcome 12 - Life-long learning: The student should be able to recognize knowledge and skill deficits that exist in the effective delivery of health care needs of the patient/society. As a life-long learner, student should be able to identify and analyze issues emerging in the advancing healthcare delivery, and set learning goals, locate, interpret appropriate resources, and assess progress toward meeting learning goals.

COURSE HAND OUT 2023-24**Class: V Pharm. D****I Course Details**

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	--	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	--	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	--	1
5.4	Clerkship *	--	--	1
5.5	Project work (Six Months)	--	20	--
	Total hours	8	20	4
	Grand Total	32 hrs/ week		

* *Attending ward rounds on daily basis.*

2. Evaluations:

Theory: Internal assessment Marks: 30. Three periodic theory sessional examinations will be conducted in theory for 30 marks (*duration 1.5 Hours*) and average of best two will be considered for evaluation.

Classes will be awarded on the basis of total (sessional and annual examination) marks secured.

Class	Marks
Distinction	75% and above
First class	60% and above and less than 75%
Second class	50% and above and less than 60%
Pass class	Passed examination in more than one attempt.

- 3 Sessional Examination schedule:** I, II and III sessional dates will be announced separately.
- 4 Attendance:** Minimum of 80% attendance is necessary to appear for both Sessional and Annual examination.
- 5 Chamber consultation hours:** Any time during College hours.
- 6 Seminar**
Objective of the seminar is to enhance the learning ability and help students in better understanding of the given topic. This provides a best opportunity for the students to clarify their subject doubts. This involves discussions, presentations on specified topics, assignments and evaluation.

5.1 CLINICAL RESEARCH

Theory: 3 Hrs / Week

Responsible member/s of the academic staff: Dr. BR Jaidev (BRJ)

Scope and Objectives: This course is designed to make the students to understand the principles and gain adequate knowledge regarding the various approaches to drug discovery including clinical phase of development. Also enables the students to understand and implement all regulatory and ethical requirements that are required during the process of drug development.

Course Outcomes:

1. Understanding basic concepts of the drug development process, how it differs from standard care, and why it is undertaken.
2. Demonstrate the competencies of clinical research designs and the regulatory approval process and apply ICH GCP guidelines in the conduct of Clinical Trials.
3. Familiarize with the various regulatory documents and guidelines and evaluate critical domestic and global regulatory and healthcare implications on product development.
4. Effectively assess and manage ethical aspects of the conduct of the clinical trial.
5. Familiarize the roles and responsibilities of the personnel involved in the conduct of clinical research to ensure that quality research is undertaken.
6. Learn to effectively handle clinical data management activities.
7. Gain and have training in the documentation of clinical trials documents.
8. Familiarize with the terminologies used in Clinical Research and know about the Standard operating procedures used in Clinical Research

Teaching/learning methodologies used:

1. Lecture
2. Discussion

2. Course material

TEXT BOOKS:

- a. Principles and practice of pharmaceutical medicine, Second edition.
Authors: Lionel. D. Edward, Aadrew. J. Flether Anthony W Fos , Peter D Sloaier
Publisher: Wiley;

- b. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
- c. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

REFERENCES:

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

Lecture wise programme

Topics	Hrs
1. Drug development process:	10
Introduction	
Various Approaches to drug discovery	
1. Pharmacological	
2. Toxicological	
3. IND Application	
4. Drug characterization	
5. Dosage form	
2. Clinical development of drug:	
1. Introduction to Clinical trials.	02
2. Various phases of clinical trial.	08
3. Methods of post marketing surveillance.	04
4. Abbreviated New Drug Application submission.	02
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines.	10
6. Challenges in the implementation of guidelines.	02
7. Ethical guidelines in Clinical Research.	02
8. Composition, responsibilities, procedures of IRB / IEC.	02

9. Overview of regulatory environment in USA, Europe and India.	10
10. Role and responsibilities of clinical trial personnel as per ICH GCP	05
a. Sponsor	
b. Investigators	
c. Clinical research associate	
d. Auditors	
e. Contract research coordinators	
f. Regulatory authority	
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment).	08
12. Informed consent Process.	02
13. Data management and its components.	05
14. Safety monitoring in clinical trials.	03

Theory Sessional examination syllabus

Sessional Number	Chapters
I	1, 2 (2.1, 2.2, 2.3)
II	2.4,2.5, 2.6, 2.7, 2.8, 2.9
III	2.10, 2.11, 2.12, 2.13, 2.14

5.2 PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Theory: 3 Hrs / Week

Responsible member/s of the academic staff: Dr Sri Harsha Chalasani (CSH)

Scope and Objectives: This course is designed to impart knowledge regarding various methods and applications of Pharmacoepidemiology and Pharmacoeconomics in drug safety monitoring, drug approval and regulations.

Course Outcomes:

- 1) Understand the principles and basic concepts of pharmacoepidemiology and its role in evaluating drug safety and effectiveness
- 2) Identify and compare the different types of studies used in pharmacoepidemiology and their relative strengths and limitations
- 3) Evaluate the design and analysis of pharmacoepidemiologic studies, including their implications for the interpretation of research findings
- 4) Understand the principles and basic concepts of Pharmacoeconomics and its role in healthcare decision-making
- 5) Identify and compare the different types of economic evaluations used in Pharmacoeconomics and their relative strengths and limitations
- 6) Evaluate the design and analysis of pharmacoeconomic studies, including their implications for the interpretation of research findings

Teaching/learning methodologies used:

1. Lecture
2. Case studies
3. Journal Club

Course materials:

REFERENCE BOOKS

1. Pharmacoepidemiology. Editors: Brian L Strom, Stephen E Kimmel, Sean Hennessy. Wiley-Black Well (Latest Edition)
2. Clinical Epidemiology- How to Do Clinical Practice Research. R. Brian Haynes, David L Sackett, Gordon H. Guyatt, Peter Tugwell, Lippinkot (Latest Edition)

3. Essentials of Pharmacoeconomics. Karen L. Rascati. Lippincott, Williams & Wilkins (Latest Edition)
4. Pharmacoeconomics and Outcomes: Applications for Patient Care: Case Studies. Editors: Grauer DW, Lee J, Odom TD, et al. American College of Clinical Pharmacy (Latest Edition)
5. Introduction to Applied Pharmacoeconomics. F. Randy Vogenberg. New York; London: McGraw-Hill (Latest Edition)

Lecture wise Programme:

	Topic	Hours
1.	Pharmacoepidemiology: Definition and scope: Origin and evaluation of Pharmacoepidemiology, need for pharmacoepidemiology, aims and applications of Pharmacoepidemiology.	06
2.	Measurement of outcomes in pharmacoepidemiology Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement	06
3.	Concept of risk in Pharmacoepidemiology measurement of risk, attributable risk, relative risk, time-risk relationship and odds ratio	06
4.	Pharmacoepidemiological methods Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods; Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case – cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.	22
5.	Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems	04
6.	Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth defects.	08
7.	Pharmacoeconomics: Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions	02 02

Pharmacoeconomic evaluation	16
Outcome assessment and types of evaluation	
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness and cost utility	
Applications of Pharmacoeconomics	03
Software and case studies (assignment discussion)	02

Theory Sessional examination syllabus

Sessional No.	Syllabus Chapters No.
I	1, 4
II	2, 3, 5, 6
III	7

5.3 CLINICAL PHARMACOKINETICS & THERAPEUTIC DRUG MONITORING

Theory: 2 Hrs/Week

Responsible member/s of the academic staff: Dr. Savitha R S (RSS)

Scope and Objectives: This course is designed to make the students to understand and apply pharmacokinetic principles in designing / individualizing dosage regimen. Also, enable the students to interpret the plasma drug range, and hepatic / renal function in optimizing the drug therapy.

Course Outcomes:

- 1) Design the drug dosage regimen based on pharmacokinetic data
- 2) Formulate individualized dosage regimens wherever appropriate
- 3) Recommend dosage adjustment for special population with altered pharmacokinetics
- 4) Manage pharmacokinetic drug interactions
- 5) Develop simple pharmacokinetic modeling for the given data using the principles of Pharmacometrics
- 6) Derive the typical protocol for therapeutic drug monitoring of individual drugs

Teaching/learning methodologies used:

1. Lecture
2. Discussion

Course materials:

REFERENCE BOOKS

- a. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring; Author: Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans Published by: Lippincott Williams & Wilkins, 2005
- b. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology By Steven How-Yan Wong, Irving Sunshine, Published by CRC Press, 1996
- c. Clinical pharmacokinetics, Author: Soraya Dhillon, Andrzej Kostrzewski, Publisher: Pharmaceutical Press

- d. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
 e. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication

Lecture wise Programme:

Topics	Hrs
1. Introduction to Clinical pharmacokinetics	01
2. Design of dosage regimens Nomograms and Tabulations in designing dosage regimen, conversion from intravenous to oral dosing, determination of dose and dosing intervals, drug dosing in the elderly and pediatrics and obese patients.	07
3. Pharmacokinetics of Drug Interaction: a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.	03
4. Therapeutic Drug monitoring a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs). c. Indications for TDM, Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following conditions: Cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.	20
5. Dosage adjustment in Renal and hepatic Disease. a. Renal impairment b. Pharmacokinetic considerations c. General approach for dosage adjustment in Renal disease. d. Measurement of Glomerular Filtration rate. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Effect of Hepatic disease on pharmacokinetics.	10
6. Population Pharmacokinetics. a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feed back. c. Analysis of Population pharmacokinetic Data.	05
7. Pharmacogenetics a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. b. Genetic Polymorphism in Drug Transport and Drug Targets. c. Pharmacogenetics and Pharmacokinetics /Pharmacodynamic considerations	04

Theory Sessional examination Syllabus

Sessional Number	Chapters
I	1,2, 3 and 7
II	4
III	5 and 6

JSS Academy of Higher Education & Research
JSS College of Pharmacy
 Sri Shivarathreshwara Nagara, Mysore-570015
CLASS TIME TABLE- 2023-24

Class: PHARM. D –FIFTH YEAR

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- 09.50AM	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	-----	-----		-	-		Pharmacoepidemiology & Pharmacoeconomics CSH	Pharmacoepidemiology & Pharmacoeconomics CSH		Case Presentation	-----
Tuesday	-----	-----	T E A	-	-	L U N C H	Pharmacoepidemiology & Pharmacoeconomics CSH	Pharmacoepidemiology & Pharmacoeconomics (Seminar) CSH	T E A	Journal Club	-----
Wednesday	-----	-----	B R E A K	-----	-----	B R E A K	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring RSS	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring RSS	B R E A K	Case Presentation	Clinical Research BRJ
Thursday	-----	-----		-----	-----		Clinical Research BRJ	Case Presentation		Clinical Research (Seminar) BRJ	-----
Friday	-----	-----		-----	-----		Clinical Research BRJ	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring (Seminar) RSS		Case Presentation	-----
Saturday	-----	-----		-----	-----						

*Effective from: 19th June - 2023

Note: 1. No tea break for practicals

Time table Coordinator
 Copy: SNB/LNB/SCF/e.copy – teachers/ Office in charge – time table / Time table coordinator

Principal

OPC8.1SOP(2)F(1)-0

