Phone: 08514 - 276211, 276212

Fax : 08514 - 276213



Email: srcp07hc@gmail.com srcn07hc@yahoo.com Web: www.srcpnandyal.edu.in

SANTHIRAM COLLEGE OF PHARMACY

Approved by AICTE & PCI, New Delhi - Affiliated to JNTUA, Anantapur NH - 18, Nandyal, Kurnool District, Andhra Pradesh - 518501.

1.2.1

Number of Programmes in Which Choice Based Credit System (CBCS/Elective Course System Has Been Implemented) Phone: 08514 - 276211, 276212 Fax: 08514 - 276213



Email: srcp07hc@gmail.com srcn07hc@yahoo.com Web: www.srcpnandyal.edu.in

SANTHIRAM COLLEGE OF PHARMACY

Approved by AICTE & PCI, New Delhi - Affiliated to JNTUA, Anantapur NH - 18, Nandyal, Kurnool District, Andhra Pradesh - 518501.

1.2.1.1

Number of Programmes in Which
Choice Based Credit System
(CBCS/Elective Course System Has
Been Implemented)
Academic year (2022-2023)



Email: srcpU/hc@gmail.com srcn07hc@yahoo.com Web: www.srcpnandyal.edu.in

SANTHIRAM COLLEGE OF PHARMACY

Approved by AICTE & PCI, New Delhi - Affiliated to JNTUA, Anantapur NH - 18, Nandyal, Kurnool District, Andhra Pradesh - 518501.

- 1.2.1 Number of Programmes in which Choice Based Credit System (CBCS)/ elective course system has been implemented
- 1.2.1.1 Number of Programmes in which CBCS/ Elective course system implemented -02 (Academic Year 2022-23)

IMPLEMENTATION OF CBCS:

S.NO	COURSE NAME	ELECTIVE SUBJECTS	ELECTED SUBJECT
	B.PHARMACY IV/II (Semester-VIII)	I) Pharma Marketing Mangement (BP803ET) II) Pharmaceutical Regulatory science (BP804ET) III) Pharmacovigilance (BP805ET) IV) Quality Control and standardization OF Herbals(BP806ET) V) Computer Aided Drug Design(BP807ET) VI) Cell and Molecular Biology(BP808ET) VII) Cosmetics Science (BP809ET) VIII) Experimental Pharmacology (BP8010ET) IX) Advanced Instrumentation Technique (BP811ET) X(Dietary Supplements and Nutraceuticals (BP812ET)	I) Pharmacovigilance (BP805ET) II) Advanced Instrumentation Technique (BP811ET)

Nam College of Phonon of P

PRINCIPAL
Santhiram College of Pharmacy
NH-40, Nandyal-518501, A.P.

Phone: 08514 - 276211, 276212 Fax: 08514 - 276213



Email: srcpU/hc@gmail.com srcn07hc@yahoo.com Web: www.srcpnandyal.edu.in

SANTHIRAM COLLEGE OF PHARMACY

Approved by AICTE & PCI, New Delhi - Affiliated to JNTUA, Anantapur NH - 18, Nandyal, Kurnool District, Andhra Pradesh - 518501.

S.NO	COURSE NAME	ELECTIVE SUBJECTS	Audit Course-I
1.	M.PHARMACY (Semester-I) 1.Pharmaceutics	I) English For Research Paper Writing (21DAC101A)	English for Research
	2.Industrial Pharmacy 3.Pharmaceutical Analysis 4.Pharmacology	II) Disaster Management (21DAC101B) Sanskrit For Technical Knowledge(21DAC101C)	

S.NO	COURSE NAME	ELECTIVE SUBJECTS	Audit Course-II
2.	M.PHARMACY (Semester-II) 1.Pharmaceutics 2.Industrial Pharmacy 3.Pharmaceutical Analysis 4.Pharmacology	PedagogyStudies(21DAC201a) Stress Management for Yoga(21DAC201b) III) Personality Development through Life Enlightenment Skills (21DAC201c)	Pedagogy Studies (21DAC201a)

S.NO	COURSE NAME	OPEN ELECTIVE SUBJECTS	OPEN ELECTED SUBJECT
3.	M.PHARMACY (Semester-III) 1.Pharmaceutics 2.Industrial Pharmacy 3.Pharmaceutical Analysis 4.Pharmacology	I) Biological Screening methods (21SOE301d) II) Pharmaceutical Validation) 21SOE301a) III) Entrepreneurship Management (21SOE301c)	1.Biological Screening methods(21SOE301d)

Santhirah College of Pharmacy NH-40, Narrdyal-518501, A.F.



Academic Regulations (R19) for
B.Pharm (Regular-Full time)
(Effective for the students admitted into I year from the Academic Year 2019-2020 onwards)

Pharmacy Council of India New Delhi

Rules & Syllabus for the Bachelor of Pharmacy (B. Pharm) Course

[Framed under Regulation 6, 7 & 8 of the Bachelor of Pharmacy (B. Pharm) course regulations 2014]

2. p. Krishnaueni 3

FRINCIPAL Chiram College of Pha

bollege of Pharmacy Abval-513501,A.P.

\$45

Table-VIII: Course of study for semester VIII

Course	Name of the course	No. of Hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management		Annual II Annual II II	
BP804ET	Pharmaceutical Regulatory Science	(9)		
BP805ET	Pharmacovigilance	3 + 3 =	1 1 1 - 2	
BP806ET	Quality Control and Standardization of Herbals			4 4-
BP807ET	Computer Aided Drug Design	0		٥
BP808LT	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraccuticals			
BP813PW	Project Work	12		6
BP814MC	Essence of India Traditional Knowledge	www.	*	*
BP815CV	Comprehensive Viva-Voce ^v – VIII	*		(46)
	Total	24	4	22

⁶Non University Examination (NUE) with grading

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	27/295/305
TI II	2.9
111	26
IV IV	2.8
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01%
Total credit points for the program	209/211°/212°

^{*} The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

Applicable ONLY for the students studied Mathematics Physics Chemistry at HSC and appearing for Remedial Biology course.

PRINCIPAL Santhiram College of Pharmacy NH-40, Nandyal-518501, A.P.

Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.



M.PHARM. IN PHARMACEUTICS COURSE STRUCTURE & SYLLABI

SEMESTER - I

S.	Course	Course Name	Hours per		Credits	
No.	codes	Course Famile	L	Т	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	1	4
2.	21S03101	Advanced Physical Pharmaceutics	4	-	120	4
3.	21S03102	Modern Pharmaceutics-I	4	-	-	4
4.	21S03103	Advanced Biopharmaceutics & Pharmacokinetics	4	1-	-	4
5.		Modern Pharmaceutical Analytical Techniques lab	-	-	6	3
6.	21S03104	Modern Pharmaceutics -I lab	-	-	6	3
7.	21DAC101b	Audit Course – I English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S03105	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER - II

C No	Course	Course Name	Н	per	Credits	
5.110.	codes			T	P	
1.	21S03201	Modern Pharmaceutics-II	4	-	1-1	4
2.	21S03202	Advanced Drug Delivery system	4	-	-	4
3.	21S03203	Industrial Pharmacy	4	-	-	4
4.	21S03204	Nano Drug Delivery system	4	-	-	4
5.	21S03205	Modern Pharmaceutics-II Lab	-	-	6	3
6.	21S03206	Advanced Drug Delivery System Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	Audit Course – II Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	4	0
8.	21S03207	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

PRINCIPAL
Santhiram College of Pharmacy
WH-40, Nandyal-518501, A. . . .



M.PHARM. IN INDUSTRIAL PHARMACY

COURSE STRUCTURE & SYLLABI

SEMESTER - I

S.	Course	Course Name	Hours per week			Credits
No.	codes		L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S03101	Advanced Physical Pharmaceutics	4	-	-	4
3.	21S08101	Pharmaceutical formulation Development	4	-	III.	4
4.	21S03103	Advanced Biopharmaceutics & Pharmacokinetics	4	-		4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	9=	-	6	3
6.	21S08102	Advanced Physical Pharmaceutics Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	Audit Course – I English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S08103	Seminar/Assignment	-	1	6	4
10000		Total	18	1	18	26

SEMESTER - II

S.No.	Course	rse Course Name	Hours per week			Credits
5.110.	codes		L	T	P	
1.	21S08201	Pharmaceutical Production Technology	4	-	-	4
2.	21S08202	Advanced Drug Delivery systems	4	-	1-	4
3.	21S08203	Pharmaceutical Industrial Management	4	-	-	4
4.	21S03204	Nano Drug Delivery systems	4	-	i. 	4
5.	21S08204	Pharmaceutical Production Technology Lab	(=)	-	6	3
6.	21S03206	Advanced Drug Delivery systems Lab	-	-	6	3
	21DAC201a 21DAC201b 21DAC201c	Audit Course – II Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-		0
8.	21S08205	Seminar/Assignment	-	1	6	4
		Total	18	1,	18	26



PRINCIPAL Santhiram Conege of Pharmacy NH-40, Nandyal-518501, A.P.



M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

SEMESTER-I

S.	Course	Course Name	Hour	eek	Credits	
No.			L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S07101	Advanced Pharmaceutical Analysis	4	-	-	4
3.	21S07102	Pharmaceutical and Food Analysis	4	-	-	4
4.	21S07103	Quality Control And Quality Assurance	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-		6	3
6.	21S07104	Pharmaceutical and Food Analysis Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	Audit Course – I English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2		-	0
8.		Seminar/Assignment	-	1	6	4
	_	Total	18	1	18	26

SEMESTER - II

S.No.	Course	Course Name	Hours per week			Credits
D.110.	codes		L	T	P	
1.	21S07201	Advanced Instrumental Analysis	4	-	-	4
2.	21S07202	Modern Bio-Analytical Techniques	4	-	-	4
3.	21SOE301a	Pharmaceutical Validation	4	-	-	4
4.	21S07203	Herbal and Cosmetic Analysis	4	-	-	4
5.	21S07204	Advanced Instrumental Analysis Lab	11-	-	6	3
6.	21S07205	Modern Bio-Analytical Techniques Lab	-	-	6	3
7.	21DAC201a 21DAC201b	Audit Course – II Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	13	0
8.	21S07206	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26



PRINCIPAL Santhiram College of Pharmacy NH-40, Nandyal-518501, A.P.



M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

SEMESTER-I

S. No.	Course	Course Name	Hour	s per v	veek	Credits
D. 110.	code		L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	_	4
2.	21S01102	Advanced Pharmacology-I	4	12		4
3.	21S01103	Clinical Pharmacology and Pharmacotherapeutics	4	-	-	4
4.	21S01104	Cellular and Molecular Pharmacology	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	1-	6	3
6.	21S01106	Advanced Pharmacology - I Lab	-	-	6	3
7.		Audit Course – I English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S01107	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER - II

S.No.	Course code	Course Name	Н	ours	oer	Credit
5.110.	Course cour		L	T	P	
1.	21S01201	Advanced Pharmacology- II	4	-)-	4
2.	21S01202	Pharmacological Screening Methods & Toxicology	4	-	T-E	4
3.	21S01203	Principles of Drug Discovery	4		-	4
		Clinical research and Pharmacovigilance	4	-	-	4
		Advanced Pharmacology -II Lab	-	-	6	3
6.	21S01206	Pharmacological Screening Methods & Toxicology Lab	-	-	6	3
7.	21DAC201a 21DAC201b	Audit Course – II Pedagogy Studies Stress Management from Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.		Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

Nandyal(Dt.)

PAINOIPAL Santhiram Chilege of Pharmacy 1.11-40, Nandyal-518501, A.P.



M.PHARM. IN PHARMACEUTICS

COURSE STRUCTURE & SYLLABI

SEMSTER - III

SNo	Course	Course Name	Ho	urs p	er	Credits
D.110.	codes			T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	-	-	4
	21SOE301d 21SOE301a 21SOE301c	Open Elective Biological Screening methods Pharmaceutical Validation Entrepreneurship Management	3	-		3
3.	21S03301	Teaching Practice/Assignment	-	-	4	2
4.	21S03302	Comprehensive viva voce	-	-	-	2
5.	21S03303	Research Work - I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course	Course Name	Hours	per w	eek	Credits
D.110.	codes	Course I want	L	T	P	
1.	21803401	Co-Curricular Activities	2			2
2.	THE RESERVE AND ADDRESS OF THE PARTY OF THE	Research Work - II	3		30	18
	21505102	Total	5		30	20

College of Spanish

Santhiram College of Pharmacy 3-1-40,Nandyal-518501,A.P.



M.PHARM. IN INDUSTRIAL PHARMACY

COURSE STRUCTURE & SYLLABI

SEMSTER - III

	Course Name Research Methodology and Intellectual Property Right Electives	4 3	T -	P -	4
			-	-	4
		3			
21SOE301a	Biological Screening methods Pharmaceutical Validation		-	-	3
21508301	Teaching Practice/Assignment	-	-	4	2
THE RESERVE OF THE PARTY OF THE	the state of the s	-	-	4	2
	Research Work - I	7	_	32	12 23
2	1SOE301c 1S08301 1S08302	1S08302 Comprehensive viva voce	1SOE301c Entrepreneurship Management 1S08301 Teaching Practice/Assignment 1S08302 Comprehensive viva voce 1S08303 Research Work - I	1SOE301c Entrepreneurship Management 1S08301 Teaching Practice/Assignment 1S08302 Comprehensive viva voce 1S08303 Research Work - I	1SOE301c Entrepreneurship Management 1S08301 Teaching Practice/Assignment - - 4 1S08302 Comprehensive viva voce - - 4 1S08303 Research Work - I 7 - 32

SEMESTER - IV

S.No.	Course	Course Name	Hours	per w	eek	Credits
5.110.	codes	Course rume	L	T	P	
1.	21508401	Co-Curricular Activities	2			2
2.		Research Work - II	3		30	18
Д.	21500102	Total	5		30	20

andyal(Dt.)

Santhiram College of Pharmacy NH-40, Nandyal-518501, A.P.



M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI SEMSTER - III

S No	Course	Course Name	Hours	per w	reek	Credits
5.110.	codes	Course I Man	L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	-	-	4
	21SOE301d 21SOE301f 21SOE301e	Open Electives Biological Screening methods Stability of Drugs and Dosage forms Pharmacoepidemiology and Pharmacoeconomics	3	-	*	3
3.	21S07301	Teaching Practice/Assignment	1 <u>2</u> 2)	-	4	2
4.	21S07302	Comprehensive viva voce	-	-	4	2
	21S07303	Research Work - I	-		24	12
	2100,000	Total	7	-	32	23

SEMESTER - IV

S.No.	Course	Course Name	Hours	per w	eek	Credits
Dirto	codes		L	T	P	
1.	21S07401	Co-Curricular Activities	2			2
2.		Research Work - II	3		30	18
	-100110	Total	5		30	20



PRINCIPAL
Santhiram College of Pharmacy
NH-40, Nandyal-518501, A.P.



M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

SEMSTER - III

S.No.	Course	Course Name	Hou	ırs pe	er	Credits
	code		L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Rights	4	-	=	4
2.	21SOE301b	Open Elective Pharmaceutical Validation Biostatistics Entrepreneurship Management	3		1	3
3.	21S01302	Teaching Practice/Assignment	-	N=	4	2
4.		Comprehensive viva voce	-	-	-	2
	21S01304	Research Work – I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course	Course Name	Hou	rs per		Credits
	code		L	T	P	
1.	21S01401	Co-Curricular Activities	2			2
2.	21S01402	Research Work – II	3		30	18
		Total	5		30	20



PRINCYPAL
Santhiram College of Pharmacy
1-40, Nandyal-518501, A.P.

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- 1. Why drug safety monitoring is important?
- 2. History and development of pharmacovigilance
- 3. National and international scenario of pharmacovigilance
- 4. Dictionaries, coding and terminologies used in pharmacovigilance
- 5. Detection of new adverse drug reactions and their assessment
- 6. International standards for classification of diseases and drugs
- 7. Adverse drug reaction reporting systems and communication in pharmacovigilance
- Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
- 9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- 10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
- 11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
- 12. CIOMS requirements for ADR reporting
- 13. Writing case narratives of adverse events and their quality.

Course Content

Unit I 10 Hours

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- · Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

Santhiram College of Pharmacy NH-40, Nandyal-518501, A.F.

- Terminologies of adverse medication related events
- · Regulatory terminologies

Unit II

10 hours

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- · WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- · Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

Unit III

10 Hours

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- · Adverse events following immunization

Pharmacovigilance methods

- Passive surveillance Spontaneous reports and case series
- Stimulated reporting
- Active surveillance Sentinel sites, drug event monitoring and registries
- Comparative observational studies Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Santhiram College 2.51950

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- · Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

Unit V

7 hours

Pharmacogenomics of adverse drug reactions

• Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

- 1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
- 2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- 3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
- 4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
- 5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
- 6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
- 7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
- 8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen, Milap C. Nahata
- 9. National Formulary of India
- 10. Text Book of Medicine by Yashpal Munjal

Santhis to college 18501. A. Santhis to college 18501. A. Santhis to college 18501.

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Course Content:

10 Hours UNIT-I

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques -Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

10 Hours UNIT-II

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-

Crystallography, rotating crystal technique, single crystal diffraction, powder

diffraction, structural elucidation and applications.

10 Hours **UNIT-III**

Calibration and validation-as per ICH and USFDA guidelines **Calibration of following Instruments**

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV 08 Hours

Radio immune assay:Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V 07 Hours

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

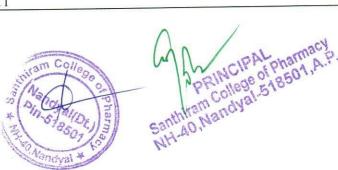
- 1. Instrumental Methods of Chemical Analysis by B.K Sharma
- 2. Organic spectroscopy by Y.R Sharma
- 3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
- 4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- 6. Organic Chemistry by I. L. Finar
- 7. Organic spectroscopy by William Kemp
- 8. Quantitative Analysis of Drugs by D. C. Garrett
- 9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- 10. Spectrophotometric identification of Organic Compounds by Silverstein

Nandyal(Dt.) Santilicam College of 8501, A. P. Santilicam College of 8501,



M.PHARM. IN PHARMACEUTICS COURSE STRUCTURE & SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semeste	•	· ·	<u> </u>	
	71 11 11 1				
	res: This course will enable students:	15-11-			
 Understa 	and the essentials of writing skills and their level of readability				
	out what to write in each section				
 Ensure q 	ualitative presentation with linguistic accuracy				
Course Outcom	es (CO): Student will be able to				
 Understa 	and the significance of writing skills and the level of readability				
	and write title, abstract, different sections in research paper				
 Develop 	the skills needed while writing a research paper			-	
IINIT - I	Research Paper- Planning and Preparation- Word Order- Useful	Lectur			
-Avoiding Ambi	es-Structuring Paragraphs and Sentences-Being Concise and Rer	Lectu			
-Avoiding Ambi	guity				
UNIT - II					m .
Essential Compo Highlight Findin	onents of a Research Paper- Abstracts- Building Hypothesis- gs- Hedging and Criticizing, Paraphrasing and Plagiarism, Caute	rizatio	n	10010	7111
UNIT - III		Lectu	re Hr		
Introducing Rev Conclusions-Rec	iew of the Literature – Methodology - Analysis of the Data-Firecommendations.	dings	- Dis	scuss	ion-
UNIT - IV		Le	ecture	Hrs	:9
	d for writing a Title, Abstract, and Introduction				
IINIT - V		12972	ecture		
Appropriate lang	guage to formulate Methodology, incorporate Results, put forth A	rgum	ents	and c	lrav
Conclusions					
Suggested Read	ling	-	1	D 1	. \
Model (t R (2006) Writing for Science, Yale University Press (available Curriculum of Engineering & Technology PG Courses [Volume-I				(S)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge U	SIAN	A A	ess	
	n N (1998), Handbook of Writing for the Mathematical Sciences,	SIAIV	1.		
Highma	n'sbook Wallwork, English for Writing Research Papers, Springer New Y	ork D	ordre	cht	





31 (2): 245-261.

2. AgrawalM(2004)Curricularreforminschools

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR (Established by Govt. of A.P., ACT No.30 of 2008) ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACEUTICS

COURSE STRUCTURE & SYLLABI

	PEDAGOGY STUDIES		T 0	P 0	0
21DAC201a		2	1.00		U
	Semester		I	I	
Course Objecti	ves: This course will enable students:				7-3-7-1
	existingevidenceonthereviewtopictoinformprogrammedesignar	ndpolic	y makir	ıg	
	ten by the DfID, other agencies and researchers. critical evidence gaps to guide the development.				
	es (CO): Student will be able to able to understand:	*			
	able to understand. lagogicalpracticesarebeingusedbyteachersinformalandinforma	alclassr	ooms in	develo	ning
countrie			001110 111	40,010	P8
	the evidence on the effectiveness of these pedagogical practic	es, in v	vhat		
	ns, and with what population of learners?				
	teachereducation(curriculumandpracticum)andtheschoolcurric	culuma	nd guida	ince	
	s best support effective pedagogy?				
UNIT - I	nd Methodology: Aims and rationale, Policy back ground,				
Thematic ove	rview: Pedagogical practices are being used by teachers eveloping countries. Curriculum, Teacher education.	in fo	rmal an	d inf	orma
Thematic ove classrooms in d		in fo	rmal an	d inf	`orma
Thematic ove classrooms in d UNIT - III Evidence on th of included stu guidance mater evidence for ef		othstage andthe	e:quality scho cu	assess rriculur	men n an
UNIT - III Evidence on the of included stuguidance mater evidence for ef	eveloping countries. Curriculum, Teacher education. eeffectivenessofpedagogicalpractices, Methodology fortheinder dies. How can teacher education (curriculumandpracticum) ials best support effective pedagogy? Theory of change. Strengfective pedagogical practices. Pedagogic theory and pedagogical practices.	othstage andthe	e:quality scho cu	assess rriculur	n an
Thematic ove classrooms in d UNIT - III Evidence on the of included stunguidance mater evidence for effattitudes and between the composition of	eeeffectivenessofpedagogicalpractices, Methodology fortheinder dies. How can teacher education (curriculumandpracticum) ials best support effective pedagogy? Theory of change. Strengfective pedagogical practices. Pedagogic theory and pedagogiliefs and Pedagogic strategies.	othstag andthe gth and gical a	e:quality scho cu I nature pproache	assess rriculur of th bo es. Tead	men n an ody o chers
Thematic ove classrooms in declar over the classrooms in declar of the classrooms in declar of the classrooms on the classrooms of the classrooms over the classrooms	eeeffectivenessofpedagogicalpractices, Methodology fortheinder dies. How can teacher education (curriculumandpracticum) ials best support effective pedagogy? Theory of change. Strengfective pedagogical practices. Pedagogic theory and pedagogiliefs and Pedagogic strategies. Evelopment: alignment with classroom practices and follow-up the head	othstag andthe gth and gical a	e:quality scho cu I nature pproache	assess rriculur of th bo es. Tead	men n an ody o chers
Thematic ove classrooms in d UNIT - III Evidence on the of included stunguidance mater evidence for effective attitudes and between the control of the con	eeeffectivenessofpedagogicalpractices, Methodology fortheinder dies. How can teacher education (curriculumandpracticum) ials best support effective pedagogy? Theory of change. Strengfective pedagogical practices. Pedagogic theory and pedagogiliefs and Pedagogic strategies. Evelopment: alignment with classroom practices and follow-up the head	othstag andthe gth and gical a	e:quality scho cu I nature pproache ort, Peer	assess rriculur of th bo es. Tead	men n an ody o chers
Thematic ove classrooms in d UNIT - III Evidence on the of included stunguidance mater evidence for effective attitudes and between the control of the con	eeeffectivenessofpedagogicalpractices, Methodology fortheinder dies. How can teacher education (curriculumandpracticum) ials best support effective pedagogy? Theory of change. Strengfective pedagogical practices. Pedagogic theory and pedagogliefs and Pedagogic strategies. Evelopment: alignment with classroom practices and follow-up the head ommunity. Curriculumandassessment, Barrierstolearning: limited and future directions: Researchdesign, Contexts, Pedagogy, Teachassessment, Dissemination and research impact.	othstag andthe gth and gical a	e:quality scho cu I nature pproache ort, Peer	assess rriculur of th bo es. Tead	men n an ody o chers



M.PHARM. IN PHARMACEUTICS COURSE STRUCTURE & SYLLABI

3. Curriculum Studies, 36 (3): 361-379.

 AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.

5. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count? International Journal Educational Development, 33 (3): 272–282.

 Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.

Chavan M (2003)ReadIndia: A mass scale, rapid, 'learning to read' campaign.

7. www.pratham.org/images/resource%20working%20paper%202.pdf.





M.PHARM. IN PHARMACEUTICS COURSE STRUCTURE & SYLLABI

Course Code	BIOLOGICAL SCREENING METHODS	LT	P	(
21SOE301d	(Elective)	3 0	0	
	Semester	III		
Course Objectives:				
	g to study about various techniques for screening of drugs			
	logical activities and guide lines for handling animals and huma	an and ar	nimal	
ethics for screening o				
	CO): Student will be able to			
	es are students will know how to handle animals and know			
	ues for screening of drugs for different pharmacological activit	ies, guid	elines	
	reening new drug molecules on animals.			
UNIT - I				
Drug discovery proce	ss: Principles, techniques and strategies used in new drug disco	very. Hi	gh	
	, human genomics, robotics and economics of drug discovery, I			
Alternatives to anima	l screening procedures, cell-line, patch -clamp technique, In-vi	tro mode	els,	
molecular biology tec				
UNIT - II	1			
Bioassays: Basic prin	ciples of bioassays, official bioassays, experimental models and	d statistic	al	
designs employed in	biological standardization.			
UNIT - III	3			_
	evaluations, ED50, LD50 and TD values, International guidelin	nes (ICH		_
recommendations).	, , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , , ,			
,	eneral principles and procedures involved in acute, sub-acute, c	hronic,		
	enicity and carcinogenicity	,		
UNIT - IV	, and a second s			_
	t classes of drugs using micro-organisms. Vitamin and antibioti	c assavs.		
	volved in toxins and pathogens.			
UNIT - V				
Enzymatic screenin	g methods: α-glucosidase, α- amylase, DNA polymer	rase, ni	uclease	es
Lasparginase, lipases	and peptidases.			
Reference Books:				
1. Basic and clinical p	pharmacology by Bertram G. Katzung (International edition) land	nge medi	cal	
book / Mc Graw Hill,	USA 2001 8th edition			
2. Pharmacology by F	Rang H.P, Dale MM and Ritter JM., Churchill Livingston, Lond	lon, 4/e		
2 Candman and Cilm	an's The phermanelagical basis of therenouties (International	dition) N	10	

3. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc Graw Hill, USA 2001 10th edition.

4. General and applid toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.

5. Drug Discovery by Vogel's

6. Drug Discovery and evaluation - Pharmacological assays by H.Gerhard. Vogel, 2nd edition, Springer verlag, Berlin, Heidelberg.

7. Tutorial Pharmacy (Vol I and II) by Cooper and Gunns.





M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Objectives: The main purpose of the subject is to understand about validation and how it condustry and thus to improve the quality of the products. The subject covers the about validation, types, methodology and application Course Outcomes (CO): Student will be able to Explain the aspect of validation Carryout validation of manufacturing processes Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities UNIT - I Introduction: Definition of Qualification and Validation, Advantage of Validualification, Design Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, TIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beau UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation (CIP). UNIT - V		L	T	P	C
Course Objectives: The main purpose of the subject is to understand about validation and how it condustry and thus to improve the quality of the products. The subject covers the about validation, types, methodology and application Course Outcomes (CO): Student will be able to Explain the aspect of validation Course Outcomes (CO): Student will be able to Explain the aspect of validation Course Outcomes (CO): Student will be able to Explain the aspect of validation Course Outcomes (CO): Student will be able to Explain the aspect of validation Course Outcomes (CO): Student will be able to Explain the aspect of validation processes Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities UNIT - I Qualification & Validation process and Validation, Advantage of Validation and Validation Master Plan. Qualification and Validation Master Plan. Qualification descriptions of Autority State Autority State Autority Acceptance Test (FAT)/ Site Autority Acceptance Test (FAT)/ Site Autority State		3	0	0	3
The main purpose of the subject is to understand about validation and how it condustry and thus to improve the quality of the products. The subject covers the about validation, types, methodology and application **Course Outcomes** (CO): Student will be able to **Explain the aspect of validation **Carryout validation of manufacturing processes **Apply the knowledge of validation to instruments and equipments **Validate the manufacturing facilities** UNIT - I **Introduction: Definition of Qualification and Validation, Advantage of Validation, Design Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis appetrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beau UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation designed in cleaning. Cleaning of Equipment. Cleaning of Dace (CIP).	ter		I	II	
The main purpose of the subject is to understand about validation and how it condustry and thus to improve the quality of the products. The subject covers the about validation, types, methodology and application **Course Outcomes** (CO): Student will be able to **Explain the aspect of validation **Carryout validation of manufacturing processes **Apply the knowledge of validation to instruments and equipments **Validate the manufacturing facilities** UNIT - I **Introduction: Definition of Qualification and Validation, Advantage of Validation, Design Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis appetrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beau UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation designed in cleaning. Cleaning of Equipment. Cleaning of Dace (CIP).					
ndustry and thus to improve the quality of the products. The subject covers the about validation, types, methodology and application • Explain the aspect of validation • Carryout validation of manufacturing processes • Apply the knowledge of validation to instruments and equipments • Validate the manufacturing facilities UNIT - I Introduction: Definition of Qualification and Validation, Advantage of Validation, Design Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, TIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beau UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation (CIP).		1	1. 1.	200	
Dourse Outcomes (CO): Student will be able to Explain the aspect of validation Carryout validation of manufacturing processes Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities DNIT - I Introduction: Definition of Qualification and Validation, Advantage of Validation waster Plan. Qualification & Validation process and Validation Master Plan. Qualification, Design Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification, Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, TIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beaunification of Instruments and Instruments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation (CIP).	n be	appl	hed t	0	:
Explain the aspect of validation Explain the aspect of validation Carryout validation of manufacturing processes Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities UNIT - I Introduction: Definition of Qualification and Validation, Advantage of Validation waster Plan. Qualification & Validation process and Validation Master Plan. Qualification, Desciping Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification, Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Visite Spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beau UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validate (CIP).	com	piete	e inic	ormai	1011
 Explain the aspect of validation Carryout validation of manufacturing processes Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities UNIT - I Introduction: Definition of Qualification and Validation, Advantage of Valid Qualification & Validation process and Validation Master Plan. Qualification Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site A Installation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beau UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appara Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation (Cleaning Validation of Equipment). 					_
Carryout validation of manufacturing processes Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities UNIT - I Troduction: Definition of Qualification and Validation, Advantage of Validation, Design Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification, Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, ETIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beau UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appara Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation (CIP).					
Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities UNIT - I Introduction: Definition of Qualification and Validation, Advantage of Validation & Validation process and Validation Master Plan. Qualification Expecification, Design Qualification, Factory Acceptance Test (FAT)/ Site A Installation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, ETIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beautonic tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validatical method used in cleaning. Cleaning of Equipment. Cleaning of place (CIP).					
Validate the manufacturing facilities UNIT - I Introduction: Definition of Qualification and Validation, Advantage of Validation & Validation process and Validation Master Plan. Qualification Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Anstallation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vistical Spectrophotometer, ETIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beautification of Iaboratory equipments: Hardness tester, Friability test apparalisintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation United Incomplete Cleaning of Equipment. Cleaning of Dace (CIP).					
UNIT - I Introduction: Definition of Qualification and Validation, Advantage of Validation & Validation process and Validation Master Plan. Qualification Epecification, Design Qualification, Factory Acceptance Test (FAT)/ Site A Installation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Visit Epectrophotometer, ETIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beautification of Instruments: Hardness tester, Friability test apparalisintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation analytical method used in cleaning. Cleaning of Equipment. Cleaning of Dace (CIP).					
Introduction: Definition of Qualification and Validation, Advantage of Validation & Validation process and Validation Master Plan. Qualification Expecification, Design Qualification, Factory Acceptance Test (FAT)/ Site A Installation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis Expectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beautification of laboratory equipments: Hardness tester, Friability test apparausintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation analytical method used in cleaning. Cleaning of Equipment. Cleaning of place (CIP).					
Qualification & Validation process and Validation Master Plan. Qualification Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site A Installation Qualification, Operational Qualification, Performance Qualification Maintaining status -Calibration Preventive Maintenance, Change manager Manufacturing Equipment, Qualification of Analytical Instruments and Labora UNIT - II Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, ETIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beautification of laboratory equipments: Hardness tester, Friability test appara Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).					
Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, ETIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beautification of laboratory equipments: Hardness tester, Friability test apparaisintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).	cepta on, l ent),	ance Re- Qu	Tes Qual	t (SA lifica cation	tio
Qualification of analytical instruments: Electronic balance, pH meter, UV-Vis spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, bea UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).	ory e	equij	pmer	its	
Spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, bea UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).					
TIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, bea UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Va of analytical method used in cleaning. Cleaning of Equipment. Cleaning of place (CIP).	ole				
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, bea UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Va of analytical method used in cleaning. Cleaning of Equipment. Cleaning of place (CIP).					
UNIT - III Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).		and I	hurat	to	
Qualification of laboratory equipments: Hardness tester, Friability test appar Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and used in cleaning. Cleaning of Equipment. Cleaning of Dace (CIP).	ers a	T	Juici	ic.	
Disintegration tester, Dissolution test apparatus. Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and the properties of analytical method used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).	tuc 1	ton	danci	ty to	tor
Validation of Utility systems: Pharmaceutical water system & pure steam, HV Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and the properties of analytical method used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).	us, i	tap c	101131	ty ics	ici
Compressed air and nitrogen. UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and the properties of analytical method used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).	CSI	vster	n		
UNIT - IV Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and Incident Cleaning of Equipment. Cleaning of Equipment. Cleaning of Equipment. Cleaning of Equipment.	10 3)	yster	11,		
Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation in the state of analytical method used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).		T			
of analytical method used in cleaning. Cleaning of Equipment. Cleaning of blace (CIP).	idati	ion a	and v	alida	tio
place (CIP).	acil	ities	. Cle	aning	g ii
JINII - V					
Analytical method validation: General principles, Validation of analytical metaguidelines and USP.	od as	s per	ICH	I	
Textbooks:					

- 1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
- 2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
- 3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
- 4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
- 5. Michael Levin, Pharmaceutical Process Scale Up Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

36