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



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SANTHIRAM COLLEGE OF PHARMACY

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1.2.1

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

: 08514 - 276213



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1.2.1.1

Number of Programmes in Which Choice Based Credit System (CBCS/Elective Course System Has Been Implemented) Academic year (2023-2024)

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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 -01 (Academic Year 2023-24)

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

S.NO	COURSE NAME	ELECTIVE SUBJECTS	Audit Comme II
2.	M.PHARMACY (Semester-II) 1.Pharmaceutics 2.Industrial Pharmacy 3.Pharmaceutical Analysis 4.Pharmacology	I) PedagogyStudies(21DAC201a) II) Stress Management for Yoga(21DAC201b) III) Personality Development through Life Enlightenment Skills (21DAC201c)	Audit Course-II 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) 2.Pharmaceutical Validation) 21SOE301a)

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M.PHARM. IN PHARMACEUTICS COURSE STRUCTURE & SYLLABI

SEMESTER-I

S.	Course	Course Name	H	Iours	per	Credits
No.	codes		L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S03101	Advanced Physical Pharmaceutics	4	-	-	4
3.	21S03102	Modern Pharmaceutics-I	4	-	-	4
4.	21S03103	Advanced Biopharmaceutics & Pharmacokinetics	4	-		4
5.	21S01105	Modern Pharmaceutical Analytical Techniques lab	-	-	6	3
6.	21S03104	Modern Pharmaceutics -I lab	-	-	6	3
	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

S.No.	To the same of the	Course Name	Н	ours	per	Credit
	codes			T	P	
1.	21S03201	Modern Pharmaceutics-II	4	-	-	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	1-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	Audit Course – II Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S03207	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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New York Nandyal-518501, A.J.



M.PHARM. IN INDUSTRIAL PHARMACY

COURSE STRUCTURE & SYLLABI

SEMESTER - I

S.	Course	Course Name	Hour	s 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	-	-	4
4.	21S03103	Advanced Biopharmaceutics & Pharmacokinetics	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	-	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
		Total	18	1	18	26

SEMESTER - II

S.No.		Course Name	Hour	s per	week	Credits
	codes		L	T	P	
1.	21S08201	Pharmaceutical Production Technology	4	-	-	4
2.	21S08202	Advanced Drug Delivery systems	4	-	-	4
3.	21S08203	Pharmaceutical Industrial Management	4	-	-	4
4.	21S03204	Nano Drug Delivery systems	4	-	-	4
5.	21S08204	Pharmaceutical Production Technology Lab	-	-	6	3
6.	21S03206	Advanced Drug Delivery systems Lab	-	-	6	3
7.	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
				1/1		

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

SEMESTER-I

S.	Course	Course Name	Hou	s per w	eek	Credits
No.	codes		L	T	P	1
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	Hou	rs per	week	Credits
	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	-	-	6	3
6.	21S07205	Modern Bio-Analytical Techniques Lab	-	-	6	3
	21DAC201b	Audit Course – II Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S07206	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

SEMESTER-I

S. No.	A CONTRACTOR OF THE CONTRACTOR	Course Name	Hou	rs per	week	Credits
	code		L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S01102	Advanced Pharmacology-I	4	-	-	4
3.	21S01103	Clinical Pharmacology and Pharmacotherapeutics	4	-	-	4
4.	21S01104	Cellular and Molecular Pharmacology	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	-	6	3
6.	21S01106	Advanced Pharmacology – I Lab	-	-	6	3
-	21DAC101b	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	Credits
			L	T	P	
1.	21S01201	Advanced Pharmacology- II	4	-	-	4
2.	21S01202	Pharmacological Screening Methods & Toxicology	4	-	-	4
3.	21S01203	Principles of Drug Discovery	4	-	-	4
4.	21S01204	Clinical research and Pharmacovigilance	4	-	-	4
5.	21S01205	Advanced Pharmacology -II Lab	-	-	6	3
6.	21S01206	Pharmacological Screening Methods & Toxicology Lab	-	-	6	3
	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

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COURSE STRUCTURE & SYLLABI

SEMSTER - III

S.No.	Course codes	Course Name	Ho	urs p	er	Credits
	12/20/20/20/20			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	reek	Credits
			L	T	P	
1.	21S03401	Co-Curricular Activities	2	_		2
2.	21S03402	Research Work - II	2	-	0.0	
			3		30	18
		Total	5		30	20

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COURSE STRUCTURE & SYLLABI

SEMSTER - III

S.No.		- Thirt		Hours per week		
	codes		L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	-	-	4
2.	21SOE301d 21SOE301a	Electives Biological Screening methods Pharmaceutical Validation Entrepreneurship Management	3	-	-	3
		Teaching Practice/Assignment	-	-	4	2
		Comprehensive viva voce	-	-	4	2
3,	21S08303	Research Work - I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course	Course Name	Hours	per w	eek	Credits
-	codes		L	T	P	
1.	21S08401	Co-Curricular Activities	2			2
2.	21S08402	Research Work - II	3		30	18
		Total	5		30	20

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M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI SEMSTER - III

S.No.	Course	Course Name	Hours	s per v	veek	Credits
_			L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	1 -	-	4
	21SOE301d 21SOE301f 21SOE301e	Open Electives Biological Screening methods	3	-	-	3
3.	21S07301	Teaching Practice/Assignment		+-	-	^
4.	21S07302	Comprehensive viva voce	+	+-	4	2
	21S07303	Research Work - I		-	4	2
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course	Course Name	Hours	per w	eek	Credits
	STATE OF THE PARTY		L	T	P	
1.	21S07401	Co-Curricular Activities	2	_		2
2.	21S07402	Research Work - II	2		20	10
		Total	3		30	18
		1000	5		30	20



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COURSE STRUCTURE SYLLABI

SEMSTER - III

S.No.	Course	Course Name	Hou	rs n	Ar.	Credits
1.	21DRM101	Research Methodology and Intellectual Property Rights	L	T	P	Creans
2.		Open Elective	4	-	-	4
	21SOE301a 21SOE301b	Pharmaceutical Validation Biostatistics Entrepreneurship Management	3	-	-	3
3.	21S01302	Teaching Practice/Assignment				
	21301303	Comprehensive viva voce	-	-	4	2
	21S01304	Research Work – I	-	-	-	2
		Total	-		24	12
			7	-	32	23

SEMESTER - IV

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

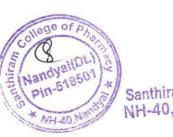


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M.PHARM. IN PHARMACEUTICS COURSE STRUCTURE & SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	•		<u> </u>	_
Course Objectiv	es: This course will enable students:				
Understa	nd the essentials of writing skills and their level of readability				
	out what to write in each section				
 Ensure quality 	ualitative presentation with linguistic accuracy				
	es (CO): Student will be able to				
 Understa 	nd the significance of writing skills and the level of readability				
 Analyze 	and write title, abstract, different sections in research paper				
	the skills needed while writing a research paper				
UNIT - I		ectur	e Hrs	:10	
		ectur	e Hrs	:10	
-Avoiding Ambig	I	ectur			
Highlight Finding	nents of a Research Paper- Abstracts- Building Hypothesis-R s- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauteri	zatio	1		11 .
UNIT - III		ectur			
Conclusions-Reco	ew of the Literature – Methodology - Analysis of the Data-Find ommendations.	ings	- Dise	cussi	on-
UNIT - IV		Lec	cture	Hrs:9)
Key skills needed	for writing a Title, Abstract, and Introduction				
UNIT - V			cture		
Appropriate langu Conclusions	age to formulate Methodology, incorporate Results, put forth Ar	gume	nts a	nd dr	aw
Suggested Readi	ng				
1 0 111 4	R (2006) Writing for Science, Yale University Press (available or	Goo	gle B	ooks)
1. Goldbort					
Model Cu	rriculum of Engineering & Technology PG Courses [Volume-I]				
Model Cu 2. Day R (20	006) How to Write and Publish a Scientific Paper, Cambridge Uni			ess	
Model Cu 2. Day R (20	006) How to Write and Publish a Scientific Paper, Cambridge Uni N (1998), Handbook of Writing for the Mathematical Sciences, S			ess	



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COURSE STRUCTURE & SYLLABI

/ 111/4 / ////		PEDAGOGY STUDIES	L	T	P	C
21DAC201a			2	0	0	0
		Semester]	I	
Course Objectiv	ves: This cour	se will enable students:				
Reviewe	xistingeviden	ceonthereviewtopictoinformprogrammedesigna	ndpolic	y makir	ng	
undertak	ten by the DfII	D, other agencies and researchers.		- A		
 Identify 	critical eviden	nce gaps to guide the development.				
		lent will be able to				
Students will be	able to unders	stand:				
		icesarebeingusedbyteachersinformalandinform	alclassr	ooms in	develo	oing
countries						
		on the effectiveness of these pedagogical practic	ces, in w	hat		
		hat population of learners?				
		ion(curriculumandpracticum)andtheschoolcurri	culumai	nd guida	ance	
UNIT - I	s best support	effective pedagogy?				
			_	1.0		
		ogy: Aims and rationale, Policy back ground,				
terminology	Theories	oflearning, Curriculum, Teachereducation. Con	nceptual	framew	ork,Res	earcl
questions. Overv	view of metho	odology and Searching.				
V10022000000000000000000000000000000000						
UNIT - II						
		ogical practices are being used by teachers ntries. Curriculum, Teacher education.	in for	mal an	d info	orma
UNIT - III						-
UNIT - III Evidence on the	reffectiveness		nthstage	·anality	2556551	men
Evidence on the		ofpedagogicalpractices,Methodologyfortheinde				
Evidence on the of included stud	dies. How car	ofpedagogicalpractices,Methodologyfortheinden teacher education (curriculumandpracticum)	andthes	cho cui	rriculun	and
Evidence on the of included stud guidance materia	dies. How car als best suppo	ofpedagogicalpractices,Methodologyfortheinden teacher education (curriculumandpracticum) ort effective pedagogy? Theory of change. Stren	andthes gth and	nature	rriculun of th bo	and dy o
Evidence on the of included studence material evidence for eff	dies. How car als best suppo fective pedago	ofpedagogicalpractices, Methodology for the independent teacher education (curriculum and practicum) or teffective pedagogy? Theory of change. Strengical practices. Pedagogic theory and pedagogic theory and pedagogic theory and pedagogic theory.	andthes gth and	nature	rriculun of th bo	and dy o
Evidence on the of included stud guidance materia	dies. How car als best suppo fective pedago	ofpedagogicalpractices, Methodology for the independent teacher education (curriculum and practicum) or teffective pedagogy? Theory of change. Strengical practices. Pedagogic theory and pedagogic theory and pedagogic theory and pedagogic theory.	andthes gth and	nature	rriculun of th bo	and dy o
Evidence on the of included stud guidance materia evidence for eff attitudes and bel	dies. How car als best suppo fective pedago	ofpedagogicalpractices, Methodology for the independent teacher education (curriculum and practicum) or teffective pedagogy? Theory of change. Strengical practices. Pedagogic theory and pedagogic theory and pedagogic theory and pedagogic theory.	andthes gth and	nature	rriculun of th bo	and dy o
Evidence on the of included studence material evidence for eff attitudes and bel	dies. How car als best suppo fective pedago liefs and Pedago	ofpedagogicalpractices, Methodology for the independent teacher education (curriculum and practicum) or teffective pedagogy? Theory of change. Strengical practices. Pedagogic theory and pedagogic theory and pedagogic theory and pedagogic theory.	andthes gth and gical ap	nature oproache	rriculum of th bo es. Teac	dy o
Evidence on the of included studence material evidence for eff attitudes and bel	dies. How car als best suppo fective pedago liefs and Pedago evelopment: a	ofpedagogicalpractices, Methodology for the independent teacher education (curriculum and practicum) or teffective pedagogy? Theory of change. Strengical practices. Pedagogic theory and pedagogogic strategies.	andthes gth and gical ap	nature oproache	rriculum of th bo es. Teac	dy o
Evidence on the of included studence material evidence for eff attitudes and bel UNIT - IV Professional des Support from the	dies. How car als best suppo fective pedago liefs and Pedago evelopment: a e head	ofpedagogicalpractices, Methodology for the independent teacher education (curriculum and practicum) or teffective pedagogy? Theory of change. Strengical practices. Pedagogic theory and pedagogogic strategies.	andthes gth and gical ap p suppo	nature opproache	rriculum of th bo es. Teac support	dy o
Evidence on the of included studence material evidence for eff attitudes and bel UNIT - IV Professional de Support from the teacherandtheconsizes	dies. How car als best suppo fective pedago liefs and Pedago evelopment: a e head	ofpedagogicalpractices,Methodologyfortheinden teacher education (curriculumandpracticum) ort effective pedagogy? Theory of change. Strenogical practices. Pedagogic theory and pedagogogic strategies.	andthes gth and gical ap p suppo	nature opproache	rriculum of th bo es. Teac support	dy o
Evidence on the of included stude guidance material evidence for eff attitudes and bel UNIT - IV Professional de Support from the teacherandthecome	dies. How car als best suppo fective pedago liefs and Pedago evelopment: a e head	ofpedagogicalpractices,Methodologyfortheinden teacher education (curriculumandpracticum) ort effective pedagogy? Theory of change. Strenogical practices. Pedagogic theory and pedagogogic strategies.	andthes gth and gical ap p suppo	nature opproache	rriculum of th bo es. Teac support	dy o
Evidence on the of included studence for eff attitudes and belattitudes and belattitudes and decomposition of the support from the teacher and the consizes	dies. How car als best suppo fective pedago liefs and Pedago evelopment: als e head mmunity.Curr	ofpedagogicalpractices, Methodology for the independent teacher education (curriculum and practicum) or the effective pedagogy? Theory of change. Strengical practices. Pedagogic theory and pedagogogic strategies. lignment with classroom practices and follow-uniculum and assessment, Barriers to learning: limite	andthes gth and gical ap p suppo dresource	rt, Peer	rriculum of th bo es. Teac support	an an dy o
Evidence on the of included studence for eff attitudes and belattitudes and belattitudes and belattitudes and description of the support from the teacher and the consizes UNIT - V Researchgapsan	dies. How car als best suppo fective pedago liefs and Pedago velopment: a e head mmunity.Curr	ofpedagogicalpractices,Methodologyfortheinden teacher education (curriculumandpracticum) ort effective pedagogy? Theory of change. Strenogical practices. Pedagogic theory and pedagogogic strategies.	andthes gth and gical ap p suppo dresource	rt, Peer	rriculum of th bo es. Teac support	dy o

Suggested Reading

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.

31 (2): 245-261.

2. AgrawalM(2004)Curricularreforminschools Themportanceofevaluation, Journal of

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M.PHARM. IN PHARMACEUTICS COURSE STRUCTURE & SYLLABI

- 3. Curriculum Studies, 36 (3): 361-379.
- 4. 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	L	T	P	C
21SOE301d	(Elective)	3	0	0	3
	Semester		I	II	22-14-
Course Objectives:					
	ng to study about various techniques for screening of drugs				
for various pharmaco	ological activities and guide lines for handling animals and huma	an ar	nd an	imal	
ethics for screening of					
	CO): Student will be able to				
	nes are students will know how to handle animals and know				
about various technic	ques for screening of drugs for different pharmacological activit	ies, g	guide	lines	É
	creening new drug molecules on animals.				
UNIT - I					
Drug discovery proc	ess: Principles, techniques and strategies used in new drug disco	very	. Hig	gh	
throughput screening	s, human genomics, robotics and economics of drug discovery, I	Regu	lation	ns.	
	al screening procedures, cell-line, patch -clamp technique, In-vi	tro n	node	ls,	
molecular biology te	chniques				
UNIT - II					
	nciples of bioassays, official bioassays, experimental models and	d stat	tistica	al	
designs employed in	biological standardization.				
UNIT - III					
Principles of toxicity	evaluations, ED50, LD50 and TD values, International guidelin	es (]	CH		
recommendations).					
Preclinical studies: G	eneral principles and procedures involved in acute, sub-acute, c	hron	ic,		
teratogenicity, mutag	enicity and carcinogenicity				
UNIT - IV			V2011100.40		
Screening of differen	t classes of drugs using micro-organisms. Vitamin and antibiotic	c ass	ays.		
Screening methods in	nvolved in toxins and pathogens.				
TIMITE N					
UNIT - V		en course e	T273/A973	1	
Enzymatic screenin	g methods: α-glucosidase, α- amylase, DNA polymer	ase,	nu	cleas	es,
Lasparginase, lipases Reference Books:	and peptidases.				
	shormondon ha Dorton C. W. to (L. t t 1 11t) 1		1.	1	
	pharmacology by Bertram G. Katzung (International edition) lar USA 2001 8th edition	ige n	nearc	aı	
	Rang H.P, Dale MM and Ritter JM., Churchill Livingston, Lond	00 /	1/2		
3. Goodman and Giln	nan's The pharmacological basis of therapeutics (International e	OII, 2	+/e	[a	
Graw Hill, USA 2001		anne)11) IVI	lC .	
	toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc N	Ailla	n pro	ecc	
Ltd, London.	to Meeting by D. Danamyne, T. Ividits, T. Tuttier (Eds) The Ivic is	viilid	ii pie	33	
5. Drug Discovery by	Vogel's				
	d evaluation – Pharmacological assays by H.Gerhard. Vogel, 2nd	d edi	tion		
Springer verlag, Berli	n. Heidelberg.	u cui	uion,		
7. Tutorial Pharmacy	(Vol I and II) by Cooper and Gunns.				
	() The state of t				



M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	Т	P	C
21SOE301a	(Elective)	3	0	0	3
	Semester			II]
	Semester		- 1		
Course Objectives:					
The main purpose of	the subject is to understand about validation and how it can be	appli	ed to)	
industry and thus to	improve the quality of the products. The subject covers the com-	olete	info	rmati	on
about validation, typ	es, methodology and application				
Course Outcomes (CO): Student will be able to				
	aspect of validation				
 Carryout val 	idation of manufacturing processes				
 Apply the kn 	lowledge of validation to instruments and equipments				
 Validate the 	manufacturing facilities				
UNIT - I					
Introduction: Definit	ion of Qualification and Validation, Advantage of Validation,	Stre	amli	ning	of
Qualification & Val	idation process and Validation Master Plan. Qualification: Us	ser F	Requi	ireme	ent
Specification, Design	1 Qualification, Factory Acceptance Test (FAT)/ Site Accepta	nce '	Test	(SA	T)
Installation Qualifica	ation, Operational Qualification, Performance Qualification, R	Re- C	Duali	ficati	on
(Maintaining status	-Calibration Preventive Maintenance, Change management).	Oua	lifica	ation	of
Manufacturing Equip	ment, Qualification of Analytical Instruments and Laboratory ed	quipi	ment	S	
UNIT - II					
Qualification of analy	rtical instruments: Electronic balance, pH meter, UV-Visible				
spectrophotometer,					
FTIR, GC, HPLC, HI					
Qualification of Glass	sware: Volumetric flask, pipette, Measuring cylinder, beakers ar	nd bu	irette		
UNIT - III					
Qualification of labor	ratory equipments: Hardness tester, Friability test apparatus, ta	p de	nsity	teste	er,
Disintegration tester,	Dissolution test apparatus.				
Community s	systems: Pharmaceutical water system & pure steam, HVAC sys	tem,			
Compressed air and n UNIT - IV	itrogen.				
	Ol ' William Ol I are a second				
of analytical mothers	Cleaning Validation - Cleaning Method development, Validatio	n and	d val	idatio	on
place (CIP).	used in cleaning. Cleaning of Equipment. Cleaning of Facility	ies.	Clear	ning	in
UNIT - V	T				
	idation: Ganaral principles Validation of analytical to		CII		
guidelines and USP.	lidation: General principles, Validation of analytical method as I	per 10	CH		
Textbooks:			-		_
LALDUURS.					

- 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-Upl, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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