## PROPOSED STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR BACHELOR IN PHARMACEUTICAL TEHCNOLOGY DEGREE (B. PHARMACY)

		A. <u>TH</u>	HEORY				
SL. NO.	CODE	THEORY	CONT	TACTS (F	PERIODS	/WEEK)	CREDITS
			L	Т	Р	TOTAL	
1	HU 101	HUMANITIES (Professional communication in English)	2	1	-	3	3
2	PT 101	PHARMACEUTICAL ANALYSIS	3	-	-	3	3
3	M 103 PTB 101	REMEDIAL MATHEMATICS OR REMEDIAL BIOLOGY	3	-	-	3	3
4	PT 103	PHARMACEUTICAL CHEMISTRY (INORGANIC PHARMACEUTICAL CHEMISTRY)	3	1	-	4	4
5	PT 106	PHARMACEUTICS (DISPENSING PHARMACY)	3	-	-	3	3
		Total of Theory				16	16
		B. <u>PRA</u>	CTICAL	I		I	
1	PT 191	PHARMACEUTICAL ANALYSIS Lab	-	-	3	3	2
2	PT 196	PHARMACEUTICS (DISPENSING PHARMACY) Lab	-	-	3	3	2
3	PT 193	PHARMACEUTICAL CHEMISTRY Lab	-	-	3	3	2
4	PTB 191	REMEDIAL BIOLOGY Lab*	-	-	3	3	2
		Total of Practical				12	8
		Total of Semester				28	24

## SEMISTER-I

\* Note: PTB 191 is compulsory for all students

\* Practical examination is essential as per PCI norms :

- i) Sessional
- ii) Practical examination 60



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## SEMESTER-II

		<u>A. THEORY</u>					
Sl. No.	CODE	THEORY			ACTS /WEEK)	CREDITS	
			L	Т	Р	TOTAL	
1	PT 203	PHARMACEUTICAL CHEMISTRY (PHYSICAL CHEMISTRY)	3	1	-	4	4
2	M 203	ADVANCED MATEHMATICS & ENGINEERING MECHANICS	3	1	-	4	4
3	PT 204	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY)	3	1	-	4	4
4	HU202	ENVIRONMENT & ECOLOGY	3	-	-	3	3
5	PT 202	PHARMACOGNOSY	2	1	-	3	3
6	PT 205	PHYSIOLOGY	2	1	-	3	3
		Total of Theory				21	21
		<u>B.</u> <u>PRACTICAL</u>	•	•			
1	PT 293	PHARMACEUTICAL CHEMISTRY (PHYSICAL CHEMISTRY) Lab	-	-	3	3	2
2	PT 294	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY) Lab	-	-	3	3	2
3	PT 292	PHARMACOGNOSY Lab	-	-	3	3	2
4	PT 295	PHYSIOLOGY Lab	-	-	3	3	2
	1	Total of Practical				12	8
		Total of Semester				33	29



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## SEMESTER-III

		<u>A. THEORY</u>					
Sl. No.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	Т	Р	TOTAL	
1	PT 304	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY)	3	1	-	4	4
2	PT 301	PHARMACEUTICAL ANALYSIS	3	1	-	4	4
3	PT 306	PHARMACEUTICS (PHYSICAL PHARMACY)	3	1	-	4	4
4	PT 307	PHARMACEUTICAL ENGINEERING	3	1	-	4	4
5	CS 303	BASIC ELECTRONICS & COMPUTER APPLICATION	3	1	-	4	4
6	PT-305	Anatomy, Physiology & Health Education (APHE)	3	-	-	3	3
		Total of Theory				23	23
		B. PRACTICAI	_				
1	PT 394	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY) Lab	-	-	3	3	2
2	PT 391	PHARMACEUTICAL ANALYSIS	-	-	3	3	2
3	PT 396	PHAMACEUTICS (PHYSICAL PHARMACY) Lab	-	-	3	3	2
4	PT 397	ENGINEERING DRAWING Lab	-	-	3	3	2
5	CS 393	BASIC ELECTRONICS & COMPUTER APPLICATION Lab	-	-	3	3	2
	1	Total of Practical				15	10
		Total of Semester				38	33



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## SEMESTER-IV

			1				CREDITS	
Sl. No.	CODE	THEORY		CONTACTS (PERIODS/WEEK)				
			L	Т	Р	TOTAL		
1	PT 406	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-I)	3	1	-	4	4	
2	PT 402	PHARMACOGNOSY	3	1	-	4	4	
3	PT 404	PHARMACEUTICAL CHEMISTRY (BIO-CHEMISTRY)	3	1	-	4	4	
4	PT 405	PHYSIOLOGY	3	1	-	4	4	
5	PT 407	PHARMACEUTICAL ENGINEERING	3	1	-	4	4	
		Total of Theory				20	20	
		<u>B. PRACTICAI</u>						
1	PT 496	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-I) LAB	-	-	3	3	2	
2	PT 492	PHARMACOGNOSY Lab	-	-	3	3	2	
3	PT 497	PHARMACEUTICAL ENGINEERING LAB	-	-	3	3	2	
4	PT 494	PHARMACEUTICAL CHEMISTRY (BIO-CHEMISTRY) LAB	-	-	3	3	2	
	1	Total of Practical				12	8	
		Total of Semester				32	28	



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		A. THEORY					
Sl. No.	CODE	THEORY		CO (PERIC	NTACT DDS/W		CREDITS
			L	Т	Р	TOTAL	
1	PT 506	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-II)	3	1	-	4	4
2	PT 508	PHARMACOLOGY	3	-	-	3	3
3	PT 509	PHARMACEUTICAL MICRO- BIOLOGY	3	-	-	3	3
4	PT 503	PHARMACEUTICAL CHEMISTRY (MEDICINAL CHEMISTRY)	3	1	-	4	4
5	PT 507	PHARMACEUTICAL ENGINEERING	3	-	-	3	3
6.	PT 504	PHARMACEUTICAL CHEMISTRY (BIO-CHEMISTRY)	3	-	-	3	3
		Total of Theory				20	20
		B. PRACTICA	<u>L</u>				
1	PT 596	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-II) LAB	-	-	3	3	2
2	PT 597	PHARMACEUTICAL ENGINEERING LAB	-	-	3	3	2
3	PT 599	PHARMACEUTICAL MICRO- BIOLOGY LAB	-	-	3	3	2
4	PT 593	PHARMACEUTICAL CHEMISTRY (MEDICINAL CHEMISTRY) LAB	-	-	3	3	2
	ſ	Total of Practical				12	08
Total of S	Semester					32	28



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## SEMESTER-VI

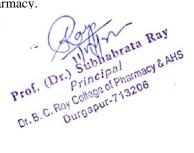
			A. THEORY					
Sl. No.	CODE	THEOI	RY			NTACT DDS/W		CREDITS
				L	Т	Р	TOTAL	
1	PT 603	PHARMACEUTICA CHEMISTRY (MEDICINAL CHEI		3	1	-	4	4
2	PT 606	PHARMACEUTICS (PHARMACEUTICA TECHNOLOGY)		3	-	-	3	3
3	PT 611	PHARMACEUTICS (BIO-PHARMACEU PHARMACOKINET	JTICS &	3	1	-	4	4
4	PT 608	PHARMACOLOGY		3	-	-	3	3
5	PT 609	PHARMACEUTICA BIO-TECHNOLOG INDUSTRIAL MICH	Y &	3	-	-	3	3
6.	PT 610A/B	ELECTIVE-I		3	-	-	3	3
	T	otal of Theory					20	20
			B. PRACTICA	<u>L</u>		I		
1	PT 693	PHARMACEUTICA CHEMISTRY (MED CHEMISTRY) LAB		-	-	3	3	2
2	PT 696	PHARMACEUTICS (PHARMACEUTICA TECHNOLOGY) LA	L	-	-	3	3	2
3	PT 697	PHARMACUTICS (BIO-PHARMACEU PHARMACOKINET			_	3	3	2
4	PT 698	PHARMACOLOGY	LAB	-	-	3	3	2
5	PT 691A/B	ELECTIVE-I						
	То	otal of Practical					12	8
			C. SESSIONAL	. <u>S</u>		1	1	L
Seminar	(PT 682)	3	3 2					
Total of	Semester	35	35 30					
Elective	т		I					

Elective-I

PT610A/691A: Computer application in Pharmaceutical Technology and in Clinical Pharmacy.

PT610B/691B: Advanced Pharmaceutical Biotechnology.

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## SEMESTER-VII

			<u>A. THEORY</u>					
Sl. No.	CODE	THEOF	RY		CO (PERIC	NTACT DDS/W		CREDITS
				L	Т	Р	TOTAL	
1	PT 706	PHARMACEUTICS (PHARMACEUTICA TECHNOLOGY)		3	-	-	3	3
2	PT 703	PHARMACEUTICA CHEMISTRY (MED CHEMISTRY)		3	-	-	3	3
3	PT 702	PHARMACOGNOS	Y	3	-	-	3	3
4	PT 708	PHARMACOLOGY		3	-	-	3	3
5	PT 709A/B/C	ELECTIVE-II		3	-	-	3	3
	Т	otal of Theory					15	15
			B. PRACTICAL	<u>L</u>				1
1	PT 796	PHARMACEUTICS (PHARMACEUTICA TECHNOLOGY) LA	L	-	_	3	3	2
2	PT 793	PHARMACEUTICA CHEMISTRY (MED CHEMISTRY) LAB	ICINAL	-	-	3	3	2
3	PT 783	PROJECT		-	-	8	8	6
	To	otal of Practical					14	10
			C. SESSIONAL	S				1
1	Seminar on assi	gned topic (PT 782)	3				2	
	Total of sessionals		3	2		2		
-	Total of Se	mester	32				27	

Elective-

PT709A: Packaging Technology

PT709B: Advanced Pharmacognosy.

PT709C: Pharmaceutical Marketing Management.



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## SEMESTER-VIII

		<u>A. THEORY</u>					
Sl. No.	CODE	THEORY		CO (PERIC	CREDITS		
			L	Т	Р	TOTAL	
1	PT 812	PHARMACEUTICAL INDUSTRIAL MANAGEMENT	3	-	-	3	3
2	PT 813	PHARMACEUTICAL JURISPRUDENCE & ETHICS	3	-	-	3	3
3	PT 818	HOSPITAL PHARMACY & CLINICAL PHARMACY	3	-	-	3	3
4	PT 801	PHARMACEUTICAL ANALYSIS	3	-	-	3	3
		Total of Theory				12	12
		B. PRACTICA	<u>[</u>	1	I		
1	PT 891	PHARMACEUTICAL ANALYSIS	-	-	3	3	2
			-	-	-	-	-
	7	Total of Practical				03	02
		C.Sessional					

1	PT 884	VIVA-VOCE	-	-	-	06	06
			-	-			
	Total of Sessional					06	06
	Tot	al of Semester				21	20

## PRECIES OF TOTAL GRADES IN B. PHARMACY PROGRAMME

SEMESTER	MINIMUM	MAXIMUM
SEM I		24
SEM II		29
SEM III		33
SEM IV		28
SEM V		28
SEM VI		30
SEM VII		27
SEM VIII		20
TOTAL CREDIT		219

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## STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR MASTER DEGREE IN PHARMACEUTICAL TEHCOLOGY ( M. PHARMA ) IN PHARMACEUTICS

## SEMESTER-I

		A. <u>THEOF</u>	<u>Y</u>					
SL. NO.	CODE	THEORY			ONTA ODS/V	CTS WEEK)	CREDITS	
			L	Т	Р	TOTAL		
01	MPT-106	Dosage form design parameters & pharmaceutical product development	4				3	
02	MBS-101	Bio-Statistics (Common paper)	4				2	
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	4				3	
04	MPT-116	Bio-pahramceutics & pharmacokinetics	3				2	
		Sessional						
05	MPT-181	Seminar					1	
06	MPT-196	Pharmaceutical Technology Lab.			4		3	
	MPT-191	Pharmaceutical Analysis Lab.			4		3	
							17	
FULL	MARKS FOR I	PAPER WITH 2 / 3 CREDIT POINT =	100		J			
FULL ]	MARKS FOR H	PAPER WITH 1 CREDIT POINT =	50					
FULL MARKS FOR PAPER WITH 5 CREDIT POINT=200								
FULL ]	MARKS FOR I	PAPER WITH 9 CREDIT POINT =	300					

## SEMISTER-II

		A. <u>THEORY</u>					
SL. NO.	CODE	THEORY			NTAC DDS/V	CTS VEEK)	CREDITS
			L	Т	Р	TOTAL	
01	MPT- 206(1)	Drug Delivery System	3				2
02	MPT-209	Pharmaceutical Bio-technology	4				3
03	MPT-212	Process validation & CGMP (Common paper)	4				3
04	MPT- 206(2)	Physical Pharmaceutics	2				1
		Sessional					
05	MPT-281	Seminar					1
06	MPT-296	Bio-pharmaceutics Lab.			4		2
							13

## SEMISTER-III

	A. <u>THEORY</u>									
SL.	CODE	THEORY		CO	CREDITS					
NO.			(	PERI	DDS/V	VEEK)				
			L	Т	Р	TOTAL				
01	MPT-314	Research Method & Clinical Trials	3				2			
02	MPT-391	Synopsis					5			
03	MPT-392	Presentation					3			
							10			

## SEMISTER-IV

		A. <u>THEORY</u>					
SL.	CODE	THEORY			NTA(		CREDITS
NO.				PERI	ODS/N	WEEK)	
			L	Т	Р	TOTAL	
01	MPT-496	Thesis					9
02	MPT- 496(1)	Defence of Thesis					3
							12
in pre	sence of Ext	presentation of 1 <sup>st</sup> semester and Thesis and Defe ernal Examiner(s). The Final Credit should be e internal and external examiners.					



Prof. (Dr.) Stabilabrata Ray Principal Dr.B. C. Roy College of Pharmacy & AHS Dr.B. C. Roy College of Pharmacy & AHS

## PROPOSED STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR MASTER DEGREE IN PHARMACEUTICAL TEHCOLOGY ( M. PHARMA ) IN PHARMACOLOGY

		A. <u>THEORY</u>					
SL. NO.	CODE	THEORY	(		NTAC DDS/V	CTS WEEK)	CREDITS
			L	Т	Р	TOTAL	
01	MPT-108(1)	General Pharmacology	4			4	3
02	MBS-101	Bio-Statistics (Common paper)	4			4	2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)	4			4	3
04	MPT-108(2)	Advanced Pharmacology	3			3	2
	•	Sessional					
05	MPT-181	Seminar					1
06	MPT-198	Pharmacology Lab			4	4	3
	MPT-191	Pharmaceutical Analysis Lab.			4	4	3
						23	17
FULL I	MARKS FOR P	PAPER WITH 2 / 3 CREDIT POINT =	100		•		

## SEMESTER-I

FULL MARKS FOR PAPER WITH 1 CREDIT POINT	=	50

FULL MARKS FOR PAPER WITH 5 CREDIT POINT=200

## FULL MARKS FOR PAPER WITH 9 CREDIT POINT = 300

## SEMISTER-II

		A. <u>THEORY</u>					
SL. NO.	CODE	THEORY			CTS WEEK)	CREDITS	
			L	Т	Р	TOTAL	
01	MPT-208(1)	Clinical Pharmacology	3			3	2
02	MPT-209	Pharmaceutical Bio-technology	4			4	3
03	MPT-212	Process validation & CGMP (Common paper)	4			4	3
04	MPT-208(2)	) Molecular Pharmacology	3			3	2
		Sessional					
05	MPT-281	Seminar					1
06	MPT-293	Pharmacology Lab.			4	4	2
						18	13

## SEMISTER-III

	A. <u>THEORY</u>										
SL.	CODE	THEORY			NTAC		CREDITS				
NO.			(	(PERIO	JDS/V						
			L	Т	Р	TOTAL					
01	MPT-314	Research Method & Clinical Trials	3			3	2				
01	MPT-391	Synopsis					5				
02	MPT-392	Presentation					3				
						3	10				

## SEMISTER-IV

		A. <u>THEORY</u>					
SL. NO.	CODE	THEORY	(		ONTAC ODS/V	CTS VEEK)	CREDITS
			L	Т	Р	TOTAL	
01	MPT-493(1)	Thesis					9
02	MPT-493(2)	Defence of Thesis					3
							12
presen	ice of External	sentation of 1 <sup>st</sup> semester and Thesis and Defe Examiner(s). The Final Credit should be tternal and external examiners.					



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## PROPOSED STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR BACHELOR IN PHARMACEUTICAL TEHCNOLOGY DEGREE (B. PHARMACY)

		A. <u>TH</u>	IEORY				
SL. NO.	CODE	THEORY	CONT	TACTS (I	PERIODS	/WEEK)	CREDITS
			L	Т	Р	TOTAL	
1	HU 101	HUMANITIES (Professional communication in English)	2	1	-	3	3
2	PT 101	PHARMACEUTICAL ANALYSIS	3	-	-	3	3
	M 103	REMEDIAL MATHEMATICS					
3		OR	3	-	-	3	3
	PTB 101	REMEDIAL BIOLOGY					
		PHARMACEUTICAL CHEMISTRY					
4	PT 103	(INORGANIC PHARMACEUTICAL CHEMISTRY)	3	1	-	4	4
5	PT 106	PHARMACEUTICS (DISPENSING PHARMACY)	3	-	-	3	3
		Total of Theory				16	16
		B. <u>PRA</u>	CTICAL				
1	PT 191	PHARMACEUTICAL ANALYSIS Lab	-	-	3	3	2
2	PT 196	PHARMACEUTICS (DISPENSING PHARMACY) Lab	-	-	3	3	2
3	PT 193	PHARMACEUTICAL CHEMISTRY Lab	-	-	3	3	2
4	PTB 191	REMEDIAL BIOLOGY Lab*	-	-	3	3	2
	ı	Total of Practical				12	8
		Total of Semester				28	24

## **SEMISTER-I**

\* Note: PTB 191 is compulsory for all students

\* Practical examination is essential as per PCI norms :

- i) Sessional :40
- ii) Practical examination : 60

## SEMESTER-II

		<u>A. THEORY</u>					
SI. No.	CODE	THEORY		CO (PERIC	NTACT DDS/W		CREDITS
			L	Т	Р	TOTAL	
1	PT 203	PHARMACEUTICAL CHEMISTRY (PHYSICAL CHEMISTRY)	3	1	-	4	4
2	M 203	ADVANCED MATEHMATICS & ENGINEERING MECHANICS	3	1	-	4	4
3	PT 204	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY)	3	1	-	4	4
4	HU202	ENVIRONMENT & ECOLOGY	3	-	-	3	3
5	PT 202	PHARMACOGNOSY	2	1	-	3	3
6	PT 205	PHYSIOLOGY	2	1	-	3	3
		Total of Theory				21	21
		<b>B. PRACTICA</b>	L				1
1	PT 293	PHARMACEUTICAL CHEMISTRY (PHYSICAL CHEMISTRY) Lab	-	-	3	3	2
2	PT 294	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY) Lab	-	-	3	3	2
3	PT 292	PHARMACOGNOSY Lab	-	-	3	3	2
4	PT 295	PHYSIOLOGY Lab	-	-	3	3	2
	1	Total of Practical				12	8
		Total of Semester				33	29

## SEMESTER-III

		<u>A. THEORY</u>					
SI. No.	CODE	THEORY		CO (PERIC	NTAC DDS/W		CREDITS
			L	Т	Р	TOTAL	
1	PT 304	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY)	3	1	-	4	4
2	PT 301	PHARMACEUTICAL ANALYSIS	3	1	-	4	4
3	PT 306	PHARMACEUTICS (PHYSICAL PHARMACY)	3	1	-	4	4
4	PT 307	PHARMACEUTICAL ENGINEERING	3	1	-	4	4
5	CS 303	BASIC ELECTRONICS & COMPUTER APPLICATION	3	1	-	4	4
6	PT-305	Anatomy, Physiology & Health Education (APHE)	3	-	-	3	3
		Total of Theory				23	23
		<u>B. PRACTICAI</u>		1	1		I
1	PT 394	PHARMACEUTICAL CHEMISTRY (ORGANIC CHEMISTRY) Lab	-	-	3	3	2
2	PT 391	PHARMACEUTICAL ANALYSIS	-	-	3	3	2
3	PT 396	PHAMACEUTICS (PHYSICAL PHARMACY) Lab	_	-	3	3	2
4	PT 397	ENGINEERING DRAWING Lab	-	-	3	3	2
5	CS 393	BASIC ELECTRONICS & COMPUTER APPLICATION Lab	-	-	3	3	2
	I	Total of Practical				15	10
		Total of Semester				38	33

## SEMESTER-IV

SI. No.	CODE	DE THEORY		CREDITS			
			L	Т	Р	TOTAL	
1	PT 406	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-I)	3	1	-	4	4
2	PT 402	PHARMACOGNOSY	3	1	-	4	4
3	PT 404	PHARMACEUTICAL CHEMISTRY (BIO-CHEMISTRY)	3	1	-	4	4
4	PT 405	PHYSIOLOGY	3	1	-	4	4
5	PT 407	PHARMACEUTICAL ENGINEERING	3	1	-	4	4
		Total of Theory				20	20
		<b>B. PRACTICAI</b>	_	I	I		I
1	PT 496	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-I) LAB	-	-	3	3	2
2	PT 492	PHARMACOGNOSY Lab	-	-	3	3	2
3	PT 497	PHARMACEUTICAL ENGINEERING LAB	-	-	3	3	2
4	PT 494	PHARMACEUTICAL CHEMISTRY (BIO-CHEMISTRY) LAB	-	-	3	3	2
	1	Total of Practical				12	8
		Total of Semester				32	28

		<u>A. THEORY</u>					
Sl. No.	CODE	THEORY			NTAC DDS/W		CREDITS
			L	Т	Р	TOTAL	
1	PT 506	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-II)	3	1	-	4	4
2	PT 508	PHARMACOLOGY	3	-	-	3	3
3	PT 509	PHARMACEUTICAL MICRO- BIOLOGY	3	-	-	3	3
4	PT 503	PHARMACEUTICAL CHEMISTRY (MEDICINAL CHEMISTRY)	3	1	-	4	4
5	PT 507	PHARMACEUTICAL ENGINEERING	3	-	-	3	3
6.	PT 504	PHARMACEUTICAL CHEMISTRY (BIO-CHEMISTRY)	3	-	-	3	3
		Total of Theory				20	20
		<b>B. PRACTICA</b>	L L				
1	PT 596	PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY-II) LAB	-	_	3	3	2
2	PT 597	PHARMACEUTICAL ENGINEERING LAB	-	-	3	3	2
3	PT 599	PHARMACEUTICAL MICRO- BIOLOGY LAB	-	-	3	3	2
4	PT 593	PHARMACEUTICAL CHEMISTRY (MEDICINAL CHEMISTRY) LAB	-	-	3	3	2
	r	Fotal of Practical				12	08
Total of S	Semester			1	<u> </u>	32	28

SEMESTER-V

## SEMESTER-VI

			<u>A. THEORY</u>					
SI. No.	CODE	THEO	RY		CO (PERIC		CREDITS	
			L	Т	Р	TOTAL		
1	PT 603	PHARMACEUTICA CHEMISTRY		3	1	-	4	4
2	PT 606	(MEDICINAL CHE) PHARMACEUTICS (PHARMACEUTIC) TECHNOLOGY)	3	3				
3	PT 611	PHARMACEUTICS (BIO-PHARMACEU PHARMACOKINET	UTICS &	3	1	-	4	4
4	PT 608	PHARMACOLOGY	3	-	-	3	3	
5	PT 609	PHARMACEUTICA BIO-TECHNOLOG' INDUSTRIAL MICI	3	-	-	3	3	
6.	PT 610A/B	ELECTIVE-I 3 3					3	
	T	Total of Theory					20	20
			<b>B. PRACTICA</b>	<u>[</u>				
1	PT 693	PHARMACEUTICA CHEMISTRY (MED CHEMISTRY) LAB	DICINAL	-	-	3	3	2
2	PT 696	PHARMACEUTICS (PHARMACEUTIC, TECHNOLOGY) LA	AL	-	-	3	3	2
3	PT 697	PHARMACUTICS (BIO-PHARMACEU PHARMACOKINET		-	3	3	2	
4	PT 698	PHARMACOLOGY	PHARMACOLOGY LAB 3			3	3	2
5	PT 691A/B	ELECTIVE-I						
	Te	otal of Practical					12	8
			C. SESSIONAL	<u>S</u>				
Seminar	(PT 682)		3				2	
Fotal of	Semester		35				30	

## Elective-I

PT610A/691A: Computer application in Pharmaceutical Technology and in Clinical Pharmacy.

PT610B/691B: Advanced Pharmaceutical Biotechnology.

## SEMESTER-VII

			A. THEORY					
SI. No.	CODE	THEOR	Y		CO (PERIC		CREDITS	
				L	Т	Р	TOTAL	
1	PT 706	PHARMACEUTICS (PHARMACEUTICA TECHNOLOGY)	(PHARMACEUTICAL				3	3
2	PT 703	PHARMACEUTICA CHEMISTRY (MEDI CHEMISTRY)	3	-	-	3	3	
3	PT 702	PHARMACOGNOSY			-	-	3	3
4	PT 708	PHARMACOLOGY	3	-	-	3	3	
5	PT 709A/B/C	ELECTIVE-II	3	-	-	3	3	
	Total of Theory						15	15
			B. PRACTICA	<u>[]</u>				
1	PT 796		PHARMACEUTICS (PHARMACEUTICAL TECHNOLOGY) LAB			3	3	2
2	PT 793	PHARMACEUTICA CHEMISTRY (MEDI CHEMISTRY) LAB		-	-	3	3	2
3	PT 783	PROJECT 8				8	6	
	Тс	otal of Practical					14	10
			C. SESSIONAL	<u>S</u>	1	1	I	
1	Seminar on assi	gned topic (PT 782)	3	3			2	
	Total of session	als	3	2				
	Total of Se	mester	32				27	

**Elective-**

PT709A: Packaging Technology

PT709B: Advanced Pharmacognosy.

PT709C: Pharmaceutical Marketing Management.

## **SEMESTER-VIII**

SI. No.					CONTACTS (PERIODS/WEEK)					
			L	Т	Р	TOTAL				
1	PT 812	PHARMACEUTICAL INDUSTRIAL MANAGEMENT	3	-	-	3	3			
2	PT 813	PHARMACEUTICAL JURISPRUDENCE & ETHICS	3	-	-	3	3			
3	PT 818	HOSPITAL PHARMACY & CLINICAL PHARMACY3-3					3			
4	PT 801	PHARMACEUTICAL ANALYSIS	3	-	-	3	3			
l		Total of Theory				12	12			
		<b>B. PRACTICA</b>	<u>L</u>			I	I			
1	PT 891	PHARMACEUTICAL ANALYSIS	-	-	3	3	2			
			-	-	-	-	-			
<b>I</b>	- -	Fotal of Practical				03	02			

## C.Sessional

1	PT 884	VIVA-VOCE	-	-	-	06	06
			-	-			
	Total of Sessional					06	06
Total of Semester						21	20

## PRECIES OF TOTAL GRADES IN B. PHARMACY PROGRAMME

SEMESTER	MINIMUM	MAXIMUM
SEM I		24
SEM II		29
SEM III		33
SEM IV		28
SEM V		28
SEM VI		30
SEM VII		27
SEM VIII		20
TOTAL CREDIT		219

## **SYLLABUS FOR B. PHARMACY**

## **SEMESTER-I**

## **PROFESSIONAL COMMUNICATION IN ENGLISH**

Code : HU 101 Contact : 2L + I T = 3 Credits: 3

#### **Guidelines for Course Execution**

#### Objective of the Course

To impart basic skills of communication in English through intensive practice to the first year UG students of Engineering so as to enable them to function confidently and effectively in that language in the professional sphere of their life.

## Desired Entry Behaviour

The student must have some basic command of English that is must be able to :

- 1. write reasonably grammatically
- 2. understand ( if not use ) at least some 2500 general purpose words of English to express himself in writing and 1500 words to talk about day-to-day events and experiences of life.
- 3. understand slowly-delivered spoken material in Standard Indian English, and
- 4. speak reasonably clearly ( if not fluently ) on routine matters with his fellow students.

#### Strategies for Course Execution

- The topics must be conveyed through plenty of examples. Lecture classes must be conducted as lecturecum-tutorial classes.
- It is a course that aims to develop skills. It is therefore "practical" in orientation. Plenty of exercises of various kinds must be done by the students both inside and outside the classroom.
- The teacher must not depend on a single or a set of two or three text books. He must choose his materials from diverse sources.
- Keeping in view the requirements of his students, the teacher may have to prepare some teaching and exercise material.
- For practice in listening, good tape recorders can be used if the more advanced facilities ( for example, language laboratory) are not available. In fact they can be used very fruitfully.
- The teacher must function as a creative monitor in the class-room.
- Minimum time should be spent in teaching phonetic symbols, stress, intonation, etc. The aim should be to enable the students to find out for himself the correct pronunciation of a word from a learner's dictionary. In teaching speaking, emphasis should be on clarity, intelligibility and reasonable fluency

rather than on " correct " pronunciation of words. Classroom presentation and group discussion sessions should be used to teach speaking.

#### **End Results from the Course**

## Some Key Concepts

Communication as sharing; context of communication; the speaker / writer and the listener / reader; medium of communication; barriers to communication; brevity, clarity and appropriateness in communication.

## Writing

Selecting material for expository, descriptive, and argumentative pieces, business letters; formal report; summarizing and abstracting; expressing ideas within a restricted word limit; paragraph division; the introduction and the conclusion; listing reference material; use of charts, graphs and tables; punctuation and spelling; semantics of connectives, modifiers and modals; variety in sentences and paragraphs.

#### **Reading Comprehension**

Reading at various speeds ( slow , fast , very fast ) ; reading different kinds of texts for different purposes (for example , for relaxation , for information , for discussion at a later stage , etc.) ; reading between the lines.

#### Speaking

Achieving desired clarity and fluency; manipulating paralinguistic features of speaking (voice quality, pitch, tone, etc.) pausing for effectiveness while speaking; task-oriented, interpersonal, informal and semiformal speaking; task-oriented, interpersonal, informal and semiformal speaking; making a short, classroom presentation.

#### **Group Discussion**

Use of persuasive strategies including some rhetorical devices ( for emphasizing , for instance; being polite and firm; handling questions and taking in criticism of self; turn-taking strategies and effective intervention ; use of body language.

Telephonic Conversation.

#### Listening Comprehension

Achieving ability to comprehend material delivered at relatively fast speed; comprehending spoken material in Standard Indian English, British English and American English; intelligent listening in institutions such as an interview in which one is a candidate.

#### **Syllabus Details:**

Grammar	_	Structure	of	sentences	_	Active	/	Passive	Voice	—	Direct	/	Indirect	Narration
										(5	lectures)			

Essay – Descriptive – Comparative – Argumentative – Thesis statement- Structure of opening / concluding paragraphs – Body of the essay

(7 lectures)

Reading Comprehension – Global – Contextual – Inferential – Select passages from recommended text (8 lectures)

Business Correspondence – Letter Writing – Formal. Drafting. Biodata- Resume'- Curriculum Vitae (7 lectures)

Report Writing – Structure, Types of report – Practice Writing

(8 lectures)

Communication / Public Speaking skills , Features of effective speech, verbal-nonverbal (7 lectures)

Group discussion – principle – practice

(6 lectures)

## **References / Books:**

- 1. Mark MaCormack : "Communication"
- 2. John Metchell "How to write reports"
- S R Inthira & V Saraswathi " Enrich your English a) Communication skills b) Academic skills " Publisher CIEFL & OUP
- 4. R.C. Sharma and K.Mohan , "Business Correspondence and Report Writing", Tata McGraw Hill , New Delhi , 1994
- 5. L.Gartside , "Model Business Letters" , Pitman , London , 1992
- Longman , "Longman Dictionary of Contemporary English" ( or 'Oxford Advanced Learner's Dictionary of Current English' , OUP , 1998.
- 7. Maxwell Nurnberg and Rosenblum Morris , "All About Words" , General Book Depot, New Delhi , 1995

Code :PT 101Contacts:3Credits :3

## **Pharmaceutical Analysis**

- 1. Significance of quantitative analysis in quality control, Different techniques of analysis, Preliminaries and definitions, Significant figures, Rules for retaining significant digits, Types of errors, Mean deviation, Standard deviation, Statistical treatment of small data sets, Selection of sample, Precision and accuracy, Fundamentals of volumetric analysis, methods of expressing concentration, primary and secondary standards.
- 2. Acid Base Titrations : Acid base concept, Selection of solvents, strengths of acids and bases, Ionization, Law of mass action, Common Ion effect, Ionic product of water, pH, Hydrolysis of salts, Henderson-Hesselbach equation, Buffer solutions, Neutralization curves, Acid-base indicators. Theory of indicators, Choice of indicators, Mixed indicators, Polyprotic system, Polyamine and amino acid systems,
- 3. **Precipitation Titrations**: Precipitation reactions, Solubility products, Effect of acids, temperature and solvent upon the solubility of a precipitate, Argentometric titrations and titrations involving ammonium or potassium thiocyanate, mercuric nitrate, and barium sulphate, Indicators, Gay-Lussac method, Mohr's method, Volhard's method and Fajan's method.

- 4. **Oxidation Reduction Titration**: Concepts of oxidation and reduction, Redox reactions, Strengths and equivalent weights of oxidising and reducing agents. Theory of redox titration, Redox indicators, Cell representations, Measurement of electrode potential, oxidation-reduction curves, Iodometry and Iodimetric Titrations involving ceric sulphate, potassium iodate, potassium bromate, potassium permanganate
- 5. **Gravimetric analysis**: Precipitation techniques, Solubility products, The colloidal state, supersaturation co-precipitation, Post-precipitation, Washing of the precipitate, Filteration, Filter papers and crucibles,Ignition, Thermogravimetric curves, Specific examples like barium sulphate, aluminium as aluminium oxide, calcium as calcium oxalate and magnesium as magnesium sulphate.

Practical

Code:	PT 191
<b>Contacts:</b>	3
Credits:	2

The students should be introduced to the main analytical tools through demonstrations. They should have a clear understanding of a typical analytical balance, the requirements of a good balance, weights, care and use of balance, methods of weighing and errors in weighing. The students should also be acquainted with the general apparatus required in various analytical procedures.

- 1. Standardization of analytical weights and calibration of volumetric apparatus.
- 2. Acid base Titration: Preparation and standardization of acids and bases, some exercises related with determination of acids and bases separately or in mixture form, some official assay procedures e.g. boric acid should also be covered.
- 3. Oxidation Reduction Titrations: Preparation and standardization of some redox titrants e.g. potassium permanganate, potassium dichromate, iodine, sodium thiosulphate, etc. some exercises related to determination of oxidizing and reducing agents in the sample shall be covered.
- 4. Precipitation titrations: Preparation and standardization of titrants like silver nitrate and ammonium thiocyanate, Titrations according to Volhard's and Fajan's method.
- 5. Gravimetric analysis: One exercise related to gravimetric analysis is to be covered.

## **Remedial Mathematics**

Theory

Code:	M 103
<b>Contacts:</b>	3L + IT
Credits: 3	

- 1. **Algebra**: Determinants of order 2,3, properties, simple problems, solution of simultaneous equations by Cramer's rule, matrices, special types of matrices, arithmetic operations on matrices, inverse of a matrix, solution of simultaneous equations by matrices, inversion method, pharmaceutical applications of determinants and matrices.
- 2. Calculus:

**Differential**: Limits, continuity of functions of a single variable derivatives, successive derivatives, Leibnitz theorem (statement only) simple problems, Lagrange's Mean Value Theorem, simple problems, evaluation of limits by L' Hospital's rule (Indeterminate form)

Partial differentiation for functions of two variables, Eculer's theorem on homogeneous functions of two variables (statement, no proof) Maxima and minima for functions of a single variable, simple problems.

## 3. Calculus :

**Integral**: Indefinite integrals of standard forms, integration by parts, method of substitution, partial fractions, formal evaluation of definite integrals.

4. **Differential Equations**: Definition and formation of differential equations, order and degree, equations of first order and first degree, variable separable, homogeneous, exact and linear differential equations and equations reducible to such types, linear differential equations of order greater than one with constant coefficients, complementary function and particular integral, pharmaceutical applications.

## OR

## **Remedial Biology**

## Code: PTB 101 Contacts: 3 Credits: 3

Theory

- 1. General idea about classification of plants, rules of priority, ICBN, brief idea about natural sexual and phyllogenetic system and classification, their merits & demerits. binomial nomenclature, taxa and taxon
- 2. **Plant Cell :** It's structure and non-living inclusions, mitosis and meiosis, different types of plant tissues and their structure, location and function.
- 3. Morphology and histology of root, stem, bark, wood, leaf, inflorescence flower, fruit and seed, Modification of root and stem.
- 4. General Survey of animal kingdom, Structure and life history & pathogenecity of parasites as illustrated by amoeba, entamoeba, trypanosoma, plasmodium, taenia, ascaris, schistosom, oxyuris, and ancylostoma.
- 5. General Structure and life history of insects like mosquito, housefly, mites (sarcoptes scabies) and silkworm.

## Practical

Code: Contacts: Credits:	PTB 191 3 2
1.	Morphology of plant parts indicated in theory.
2.	Care, use and type of microscopes.
3.	Gross identification of slides of structure and life cycle of lower plants, animals mentioned in theory.
4.	Morphology of plant parts indicated in theory.
5.	Preparation, microscopic examination of stem, root and leaf of monocot and dicot plants.
6.	Dissection of toads and identification of different organs.

#### Pharmaceutical Chemistry (Inorganic Pharmaceutical Chemistry)

Theory

Code:	PT 103
<b>Contacts:</b>	3L + 1T
Credits: 4	

An outline of methods of preparation, uses, sources of impurities, tests for purity and identity, including limit tests for iron, arsenic, lead, heavy metals, chloride, sulphate and special tests if any, of the following classes of inorganic pharmaceuticals included in **Indian Pharmacopoeia**.

- 1. Acids and Bases: Buffers :, Arrhenius concept, Lewis concept, Bronsted Lowry concept, pH, pOH, Buffer solutions, buffer capacity, physiological buffer, selection of buffer solution and role of buffer in pharmacy, Water (Types, quality, purification and preservation)
- 2. Gastrointestinal Agents: Acidifying agents (dilute hydrochloric acid), Antacids [definition, characteristics, drug interaction, compounds including aluminium hydroxide gel, dried aluminium hydroxide gel, calcium carbonate, magnesium carbonate (light & heavy), milk of magnesia, magnesium trisilicate and sodium bi-carbonate injection] Protectives and Adsorbents (mismatch sub-carbonate and bismath subgalate), Cathartics (definition and Mechanism of action of cathartics, laxatives and purgatives, Magnesium sulphate and disodium hydrogen phosphate)
- 3. Major Intra-and Extra-cellular electrolytes: Physiological ions, Electrolytes used for replacement therapy, acid-base balance and combination therapy.
- 4. Essential and Trace Elements: Transition elements and their compounds of pharmaceutical importance: Iron and haematinics, mineral supplements.
- 5. Cationic and anionic components of inorganic drugs useful for systemic effects.
- 6. Inorganic Radio pharmaceuticals: Nuclear radio pharmaceuticals. clinical applications and dosage, hazards and precautions.
- 7. Topical Agents: Protectives (silicon polymers, activated dimethicone, calamine & calamine lotion, zinc oxide), Astringents and Anti-infectives(Hydrogen peroxide, potassium permanganate, chlorinated lime, iodine solutions, sublime sulphur)
- 8. Dental Products: Dentifices, Anti-caries agents
- 9. Complexing and chelating agents used in therapy
- 10. Miscellaneous Agents: Definition and representative example of Sclerosing agents, expectorants, emetics, poisons and antidotes, sedatives etc. Pharmaceutical Aids used in Pharmaceutical Industry. Anti-oxidants, preservatives, filter aids, adsorbents, diluents, excipients, suspending agents, colorants etc.

## Practicals

Code:	PT 193
<b>Contacts:</b>	3
Credits: 2	

The background and systematic qualitative analysis of inorganic mixtures of upto four radicals, Six Mixtures to be analysed, preferably by semi-micro methods, identification tests for pharmaceutical/inorganic pharmaceuticals and qualitative tests for cations and anions should be covered.

## Pharmaceutics (Dispensing and Community Pharmacy)

Theory

Code: Contacts: Credits: 3	PT 106 2L + 1T = 3
1.	Introduction to pharmacopoei <b>Prescription</b> • Handling of

- . Introduction to pharmacopoeia and different types of pharmaceutical formulations ( definition ).
- 2. **Prescription :** Handling of prescription, source of errors in prescription, care required in dispensing procedures including labelling of dispensed products.
- 3. General dispensing procedures including labelling of dispensing products.
- 4. **Pharmaceutical calculations** : Posology, calculation of doses for infants, adults and elderly patients; calculation involving percentage solution, allegation method, alcohol dilution, proof spirit, isotonicity adjustment.
- 5. **Principles involved and procedures adopted in dispensing of :** Typical prescriptions like solution, emulsions, ointments, powders, pills, tablet triturates etc.
- 6. **Incompatibilities :** Physical, chemical and therapeutic incompatibilities. Correction of incompatibilities.
- 7. **Community Pharmacy :** Organisation and structure of retail and whole sale drug store-types of drug store and design, legal requirement for establishment, maintenance and drug store-dispensing of proprietary products, maintenance of records of retail and wholesale, patient counselling, role of pharmacist in community health care and education.

## Practical

Code:	PT 196
<b>Contacts:</b>	3
Credits: 2	

- 1. **Dispensing of prescription falling under the categories** : Mixture, solutions, emulsions, ointments, powders, suppositories, opthalmics, paste, paints, tablet titurates, lotions, liniments, etc.
- 2. Identification of various types of incompatibilities in prescription, correction thereof and dispensing of such prescriptions.

## SEMESTER -II

#### Pharmaceutical Chemistry (Physical Chemistry)

Theory

Code:	PT 203
<b>Contacts:</b>	3L + 1T
Credits: 4	

## 1<sup>st</sup> Half

- 1. Behaviour of Gases: Kinetic theory of gases, deviation from ideal behaviours and explanation.
- 2. **The Liquid State**: Physical properties (surface tension, parachor, viscosity, refractive index, optical rotation, dipole moments and chemical constituents).
- 3. **Solutions**: Ideal and real solutions, solutions of gases in liquids, colligative properties, partition coefficient, conductance and its measurement, Debye Huckel theory.
- 4. Colloids
- 5. Acids, bases and salts, pH, pka, buffers and buffering action.

6. **Thermodynamics**: First law of thermodynamics : Energy, Work, Heat, Enthalpy, Thermochemistry.

Second law of Thermodynamics : Entropy, Free Energy Net Work, deduction of important equations Clausius-calpeyron equation Helomrholtz equation, Vant Hoff equation.

Phase equilibria and phase rule.

- 7. **Adsorption :** Freudlich and Gibbs adsorption isotherms, Langmuir theory of adsorption.
- 8. **Chemical Kinetics:** Moleculerity and order of reaction, Zero, first and second order reactions, complex reactions, theories of reaction kinetics, Arrhenius equation, characteristics of homogeneous and heterogeneous catalysis, acid-base and enzyme catalysis.
- 9. Electrochemistry: electrolyte and non-electrolytes

## Practical

Code: Contacts: Credits: 2	PT 293 3
1.	To determine the refractive index of given liquids
2.	To determine the specific rotation of sucrose at various concentration and determine the intrinsic rotation.
3.	To determine the rate constant of simple reaction
4.	Determination of partition co-efficient of drugs
5.	Experiments on adsorption and colorimetry
6.	Determination of transition temperature of a salt.
7.	Determination of adsorption coefficient.
8.	Determination of surface tension and viscosity of liquids
9.	Determination of acid-base, dissociation constant by pH meter

#### **Advanced Mathematics & Engineering Mechanics**

Code:	M 203
<b>Contacts:</b>	3L + 1T
Credits: 4	

- 1. Biometrics : Exact and approximate numbers, significant digits and rounding off numbers, data collection, data organisation, diagramatic representation of data, bar, pie, 2-D and 3-D diagrams, simple measures of central tendency, mean, median, mode, simple measure of dispersion, standard Deviation and standard error of means, coefficient of variation, concept of probability, classical and frequency definition of probability, conditional and compound probability, independence of events, total, addition and multiplication theorems of probability (no proof required), simple problems of probability, Bayes Theorem (statement) and application, elements of Binomial and Poisson distributions, Normal distribution curve and properties, Kurtosis and skewness, correlation and regression lines, linear curve fitting by the method of least squares, confidence (fiducial) limits, statistical reference, Student's and paired t-test and F-test, applications of statistical concepts in Pharmaceutical Sciences.
- 2. Laplace Transforms : Definition, transforms of elementary functions, properties of linearity and shifting, inverse Laplace transforms, transforms of derivatives, solution of ordinary simultaneous differential equations (in two variables).

3. Engineering Mechanics : Composition and resolution of forces, equilibrium of concurrent forces, Polygon of forces, Friction, Sliding friction (simple problems) Centre of gravity arc, area, volume (use of calculus) simple problems, Motion under gravity, work, power, energy, conservation of Energy.

## Pharmaceutical Chemistry (Organic Chemistry)

## Theory

Code:	PT 204
<b>Contacts:</b>	3L + 1T
Credits: 4	

The subject of organic chemistry will be treated in its modern perspective keeping for the sake of conveniences, the usual classification of organic compounds :

- 1. Structure and Properties : Atomic structure, Atomic orbitals. Molecular orbital theory, Molecular orbitals, Bonding and Anbtibonding orbitals, Covalent bond, Hybrid orbitals, Intramolecular forces, Bond dissociation energy, Polarity of bonds, Polarity of molecules, structure and physical properties, Intermolecular forces.
- 2. Structure, Nomenclature, Preparation and Reactions of Alkanes, Alkenes, Alkynes, Cycloalknes, Dienes, alkyl halides.
- 3. **Stereochemistry**: Isomerism and nomenclature and associated physicochemical properties, optical activity, stereoisomerism, specification of configuration, Reactions involving stereoisomers, chirality, chiral reagents conformations.
- 4. Structure, Nomenclature, Preparation and Reactions of: Alcohols, Ethers, Epoxides, Amines, Aldehydes and ketones, Carboxylic acids.
- 5. Concept of Aromaticity

## Practicals

Code:	PT 294
<b>Contacts:</b>	3
Credits: 2	

- 1. The students should be introduced to the various laboratory techniques, through demonstrations involving synthesis of selected organic compounds (e.g. aspirin, p-bromoacetanilide, reduction of nitrobenzene etc.)
- 2. Identification of organic compounds and their derivatisation.
- 3. Introduction to the use of stereomodels.

## **ENVIRONMENT AND ECOLOGY**

 Code:
 HU 202

 Contacts:
 3L + 1 T = 4

 Credits:
 3

## General

Introduction, components of the environment, environmental degradation

## Ecology

Elements of Ecology ; Ecological balance and consequences of change, principles of environmental impact assessment

## Air Pollution and Control

Atmospheric composition, energy balance, climate, weather, dispersion, sources and effects of pollutants, primary and secondary pollutants, green house effect, depletion of ozone layer, standards and control measures.

Noxious gases and vapours (CO, Benzene, Gasoline, Kerosene)

## Water Pollution and Control

Hydrosphere, natural water, pollutants : their origin and effects, river / lake / ground water pollution, standards and control (Specifically arsenic, lead & mercury).

## Land Pollution

Lithosphere, pollutants (municipal, industrial, commercial, agricultural, hazardous solid wastes); their origin and effects, collection and disposal of solid waste, recovery and conversion methods.

## **Noise Pollution**

Sources, effects, standards and control.

# References / Books: Masters, G.M., "Introduction to Environmental Engineering and Science", Prentice –Hall of India Pvt. Ltd., 1991 Nebel, B.J., "Environmental Science", Prentice –Hall Inc., 1987

- 3. Odum , E.P., "Ecology: The Link between the natural and social sciences" , IBH Publishing Com. , Delhi
  - 1. Definition, history and scope of pharmacognosy including indigenous system of medicine.
  - 2. Various system of classification of drugs of natural origin.
  - 3. Adulteration and drug evaluation; significance of pharmacopoeial standards and different types of Extrinsic & Intrinsic factor.
  - 4. Occurrence, distribution, organoleptic evaluation, microscopical evaluation, chemical constituents including tests wherever applicable and therapeutic efficacy of following categories of drugs.
    - a) Laxatives: Aloes, Rhuburb, Castor oil, Ispaghula, Senna
    - b) Cardiotonics Digitalis,
    - c) Carminatives & G.I. regulators Coriander, Fennel, Ajowan, Cardamom, Black pepper, Nutmeg, Cinnamon, Clove.
    - d) Astringents Catechu

- 5. Occurrence, distribution, organoleptic evaluation, microscopical evaluation, chemical constituents including tests wherever applicable and therapeutic efficacy of following categories of drugs.
  - Drugs acting on nervous system Hyoscyamus, Belladonna, Aconite Ashwagandha, Ephedra, a) Opium, Cannabis, Nux vomica.
  - b) Antihypertensives - Rauwolfia
  - Antitussives Vasaka, Tulsi c)
  - Antirheumatics Colchicum d)
  - e) Antitumour - Vinca
  - Antileprotics Chaulmoogra Oil f)
  - Antidysenterics Ipecacuanha g)
  - Antiseptics and disinfectants Neem, h)
  - Antimalarials Cinchona i)
  - Oxytocics Ergot j)
  - k) Vitamins Shark liver oil

## Practical

Code: Contacts: Credits: 2	292 3	
1.	Identification of crude drugs (containing carbohydrate, lipid, glycosides, volatile oil, alkaloid etc.) by morphological characters.	
2.	Physical and chemical tests for evaluation of crude drugs wherever applicable	
3.	Microscopic studies of Senna leaf, Rauwolfia root, Cinamon bark, Datura flower and stem.	
4.	Identification of fibers and surgical dressings	
Theory	Physiology	
Code: Contacts: Credits: 3	PT 205 3	
1.	<ul> <li>Blood and cardiovascular system :</li> <li>a) The physiological properties, Physical characters, composition and functions of blood.</li> </ul>	

- The Erythrocytes, Hemoglobin, Hemolysis and suspension stability of the blood, b) leukocytes and platelets.
- The blood volume, The lymph and tissue fluids. c)
- The blood pressure. d)
- e) Cardiac muscle and its properties, special junctional tissues of heart.
  - Cardiac cycle, cardiac output, Electrocardiogram, regulation of heart's action.
- 2. Respiratory system :

- a) The mechanism of respiration, the air of the lungs, the physical principles governing the respiratory exchanges, the transport and delivery of Oxygen to the tissues. Intracellular oxidations and energy transfer, the carriage of carbon dioxide.
- b) The control of respiration, periodic respiration, dysponea, anoxia and other abnormal forms of respiration.

## 3. Excretory System :

- a) Renal circulation, Structure and Functions of kidney, Functions of glomerulus, Functions of renal tubules, renal circulation, renal function tests.
- b) Composition of Urine and the factors affecting the formation of urine, factors controlling the volume of urine.
- c) Glycosuria, Micturition.
- 4. Endocrine glands : Anatomical position, structure, function & disorder
- 5. Digestive system

## Practical

Code:	PT 295
Contacts:	3
Credits: 2	

- 1. Study of human skeleton and identification of different visceral organs
- 2. Study of different system with the help of charts and models.
- 3. Microscopic studies of different tissues and organs
- 4. Estimation of TC, DC, Hb, ESR, clotting time, bleeding time.
- 5. Recording of body temperature, pulse rate, blood pressure and brief understanding of ECG-PQRST waves and their significance.
- 6. Experimental physiology : Handling, weighing, numbering, anaesthetising and injection of mice/rat/rabbit.
- 7. Isotonic & isometric muscle contractions with special reference to temp., ion, bioactive molecules

## <u>SEMESTER – III</u>

#### Pharmaceutical Chemistry (Organic Chemistry)

## Theory

Code:	PT 304
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

## Nucleophillic aromatic substitutions: —,

- 1. Electrophilic and nucleophilic aromatic substitution
- 2. Synthesis and reaction of phenols, aromatic sulfonic acids, nitro-compound, anilines, diazonium salt, chemistry of carbohydrate

## **Polynuclear aromatic system :**

**Heterocyclic Compounds** : Nomenclature of heterocyclic compounds, Chemistry, preparations and properties of some important heterocyclis compounds containing 5,6 atoms with one or two heteroatoms like O,N,S., Napthalene, Anthracene, etc.

21

Practical

## Code: PT 394 Contacts: 3 Credits: 2

At least two exercises in synthesis involving various heterocyclic ring systems. Workshop on molecular modelling of different isomers, molecular modelling on double helical structure of nucleic acid showing hydrogen bonding.

At least 3 reactions involving eletrophilic aromatic substitutions.

## **Pharmaceutical Analysis**

## Theory

Code:	PT 301
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

Theoretical considerations, and application in drug analysis.

- 1. Non-aqueous titrations
- 2. Complexometric titrations.
- **3.** Miscellaneous Methods of Analysis : Diazotisation titrations, Kjeldahl method of nitrogen estimation, Karl-Fischer titration, Oxygen flask combustion,
- 4. Chromatography : The following techniques will be discussed with relevant examples of Pharmacopeial products. TLC, HPLC, GLC, Paper Chromatography and Column Chromatography.

Theoretical considerations, and application in drug analysis :

- 1. Potentiometry
- 2. Conductometry
- 3. Amperometry

## Practical

Code:	PT 391
<b>Contacts:</b>	3
Credits: 2	

- 1. **Non aqueous Titrations :** Preparation and standardization of perchloric acid and sodium/potassium/lithium methoxides solutions; Estimations of at least one pharmacopoeial product.
- 2. **Complexometric Titrations :** Preparation and standardization of EDTA solution, at least one exercise related to pharmacopoeial assays by complexometric titration.
- 3. **Miscellaneous Determinations :** Exercises involving Karl-Fischer, Determination of alcohol content in liquid galenical.
- 4. Experiments involving separation of drugs from excipients and estimation.
- 5. Chromatographic analysis of some pharmaceutical products.

#### Anatomy, physiology and health education(APHE)

Code:	PT 305
<b>Contacts:</b>	2L + 1T = 3
Credits: 3	

- 1. **Elementary Tissues of the Human Body** : Anatomical position, structure, characteristic & functions of Epithelial, connective, muscular and nervous tissues, their sub-types.
- 2. **Osseous System** : Structure, composition and functions of skeleton. Classification of joints, types of movements of joints, disorders of joints.
- 3. **Skeletal Muscles** : Gross anatomy, physiology of muscle, contraction, physiological properties of skeletal muscles and their disorders.
- 4. **Haemopoietic system :** Composition and functions of blood and its elements, their disorders, blood groups and their significance, mechanism of coagulation, disorders of platelets and coagulation.
- 5. **Lymph and Lymphatic system:** Composition, formulation and circulation of lymph; disorders of lymph and lymphatic system. Basic physiology and functions of spleen.
- 6. **Digestive System :** General, anatomical outline of gastrointestinal tract, function of different parts including those of liver, pancreas and gall bladder.
- 7. **Respiratory System :** Anatomy of respiratory system and organs.
- 8. Nervous System : General outline of central nervous system and autonomic nervous system.
- 9. a) **Demography and family planning** : Medical termination of pregnancy.
  - **b) Communicable diseases**: Brief outline, their causative agents, modes of transmission and prevention (Chicken pox, measles, influenza, diphtheria, tuberculosis, poliomyelitis, helminthiasis, malaria,
  - c) Filariasis, rabies, trachoma, tetanus, leprosy, syphilis, gonorrhoea and AIDS.
  - d) First Aid : Emergency treatment of shock, snake bites, burns, poisoning, fractures and resuscitation methods.

## Pharmaceutics (Physical Pharmacy)

Code:	PT 306
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

- 1. **Matter, Properties of Matter** : State of matter, change in the state of matter, Latent heat and vapor pressure, sublimation critical point, Eutectic mixtures, gases, aerosols-inhalers, relative humidity, liquid complexes, liquid crystals, glassy state, solids-crystalline, amorphous and polymorphism.
- 2. **Micromeretics and Powder Rheology**: Particle size and distribution, average particle size, number and weight distribution, particle number, methods for determining particle volume, optical microscopy, sieving, sedimentation, measurement, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.
- 3. **Surface and Interfacial Phenomenon**: Liquid interface, surface and interfacial tensions, surface free energy, measurement of surface and interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB classification, solubilization, detergency, adsorption at solid interfaces, solid gas and solid-liquid interfaces, complex films, electrical properties of interface.
- 4. **Viscosity and Rheology :** Newtonian systems, Law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling ball, rotational viscometers.
- 5. **Dispersion systems :** Colloidal dispersions : Definition, types, properties of colloids, protective colloids, applications of colloids in pharmacy; Suspensions and Emulsions: Interfacial properties of suspended particles, settling in suspensions, theory of sedimentation, effect of Brownian movement, sedimentation of flocculated particles, sedimentation parameters, wetting of particles,

controlled flocculation, flocculation in structured vehicles, rheological considerations, Emulsionstypes, theories, physical stability.

- 6. **Complexation and Protein Binding :** Classification of complexes, methods of preparation and analysis, applications. Protein binding, binding equilibrium, analysis, Thermodynamic treatment to stability constant.
- 7. **Kinetics and Drug Stability :** Half-life determination, Influence of temperature, light, solvent, catalytic species and other factors, Accelerated stability study, expiration dating, decomposition and stabilisation of medicinal agent.

## Practicals

Code:	PT 396
<b>Contacts:</b>	3
Credits: 2	

- 1. Determination of particle size, Particle size distribution and surface area using various methods of Particle size analysis.
- 2. Determination of derived properties of powders like density, porosity, compressibility, angle of repose etc.
- 3. Determination of surface/interfacial tension. HLB value and critical micellar concentration of surfactants.
- 4. Study of rheological properties of various types of systems using different Viscometers, evaluation of intrinsic viscosity of a system by viscosity determination using various concentration and if possible, determination of molar mass
- 5. Studies of different types of colloids and their properties.
- 6. Preparation of various types of suspensions and determination of their sedimentation parameters.
- 7. Preparation and stability studies of emulsions.
- 8. Accelerated stability testing, shelf-life determination and expiration dating of pharmaceuticals.
- 9. The effect of pH of the solubility on a slightly soluble weak acid.

## Pharmaceutical Engineering

Code:	PT 307
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

- 1. **Stoichiometry :** Units and their conversions, molecular units, basic laws, mole fraction, problems on stoichiometry, material balance and related problems, energy balance and related problems. Dimensional analysis, different types of graphic representations.
- 2. **Fluid Flow :** Different manometers and their application, types of flow, boundary layer concept, Reynold's number, Bernoulli's theorem, fluid friction, flow measuring devices, non-Newtonian fluid flow basic concept.
- 3. Material Handling:
  - a) Liquid handling Different types of pumps.
  - b)
  - c) Gas handling-Various types of fans, blowers and compressors.
  - d) Solid handling Bins, Bunkers, Conveyers, Other solid transport systems.

- 4. Filtration and Centrifugation : Theory of filtration, industrial filters like leaf filters, rotary filter, filter press edge filter etc. filter aids, and resistances, mathematical problems. Principles of centrifugation, centrifugal filters and sedimentors, Pharmaceutical applications.
- Industrial Hazards & Safety precautions : Different types of hazards like mechanical, electrical, 5. chemical, dust, fire etc. Preventive methods and precautions. First Aid – shock, fainting, wounds, Acid and Alkali burns, poison antidotes, artificial respiration etc.

## **Engineering Drawing**

Code:	PT 397
<b>Contacts:</b>	3
Credits: 2	

I.S. Conventions of drawing – lettering, scales etc., Orthographic Projection – first and third angle concepts Isometric drawing and Dimensioning.

Sections and Sectional Views Bolted and riveted joints Welded joints Pipe joints and fittings Types of flanges and working drawing of pulley, key etc. Pressure vessel and auxiliaries – skirt, saddle etc. Line drawing of agitator, ball mill, mixer, filter press, Centrifuge, dryer, evaporator Calandria, granulator, sieving machine, tablet compressing machine etc.

Concept of flow diagram.

#### **Computer Science and Applications**

Theory	
Code:	CS 303
<b>Contacts:</b>	3L + 1T
Credits: 4	

#### 1. **Computers Applications :**

- 1.1 Introduction to Computers. History of Computer development and respective generation: classification of computers, different parts of modern digital computer and their functions, hardware and software.
- 1.2 Number system: Binary, decimal, hexadecimal and octal number systems and their inter conversion.
- 1.3 Boolean Algebra: definition and rules, logical expressions, simplification of logical expressions (K-Map not needed). Logic Gates: Introduction to logic gates, AND, OR NOT, NOR, NAND, XOR logic gates, truth tables, simple digital circuits using logic gates.
- 1.4 Basic concept of operating system and its functions, classification, 9MS-DOS commands will be learned and used in Laboratory only)
- 1.5 Introduction to computer language, Alphabets in C

Keywords in C, Data Variables, Data Types and Rules for naming and declaring data variables, Basic Data types in C, constants, Enumerated Data Types, C Instructions and Rules for Writing Them Types of instructions

Data Manipulation Instructions Input/Output Instructions Flow control instructions **Decision Control Instructions** If If-else

If-else-if Nested if-else Conditions Loop Control Instructions For loop While loop Do while Selection Instructions Functions Components of Function Name of a function Body of a function Local variables of a function Parameters of Arguments to a function Return Values Prototype of a function Arrays What is an array? Array Declaration Array Initialization Accessing individual elements of an array Two Dimensional Arrays Accessing the elements of a two dimensional array More than two dimensions Passing an array element to a function

Simple programs using C

Practical:[Code: CS 393]Contacts :3Credits :2

- 1. Executing MS-DOS commands, creating and executing batch file, writing and executing simple programs in C.
- 2. Create tables using Oracle, insert data into the tables, update tables, modify the structure of a table, implement Foreign key and primary key constraints, Design and create a small inventory database, design and create a database of a small Hospital, Design drug-drug interaction database, retrieve different types of information using SQL.
- 3. Practical designed on the use of computers in drug information center, prescription filing and documentation of information on drug interaction.

# <u>SEMESTER – IV</u> Pharmaceutics

# (Pharmaceutical Technology-I)

Theory

Code:	PT 406
Contact:	3L + 1T = 4
Credits: 4	

- 1. Liquid dosage forms : Introduction, types of additives used in formulation, vehicles, stabilization, preservatives, suspending agents, emulsifying agents, solubilisers, colours, flavours and others; Manufacturing, packaging and evaluation.
- 2. **Semisolid dosage forms:** Definition, types, mechanism of drug penetration, factors influencing penetration, semi-solid bases and their selection, general formulation of semi-solids, clear gels manufacturing procedure, evaluation and packaging.
- 3. **Suppositories :** Definition, size, shape and doses, ideal requirements, factors affecting drug absorption, type of bases, manufacturing procedure, storage, packaging, stability of suppositories.
- 4. **Extraction and Galenical Products :** Principle and method of extraction, factors affecting extraction rate, choice extraction procedure, preparation of infusion, tinctures, dry and soft liquid extracts.
- 5. **Blood products and plasma substitutes :** Collection, processing and storage of Whole human blood and all fractions individually. Plasma substitutes ideal requirements, PVP, dextran etc. for control of blood pressure as per I.P.
- 6. **Pharmaceutical Aerosol :** Mode of operation, Definition, propellants, manufacturing and packaging methods, container with all parts, pharmaceutical application and testing.
- 7. **Ophthalmic preparation :** Requirements, eye drops, eye lotions, eye ointments, formulation, additives, preparation, sterilization, packaging, evaluation, contact lens solution.

### Practical

Code:	PT 496(1)
<b>Contacts:</b>	3P
Credits: 2	

- 1. Preparation, evaluation and packaging of liquid orals like solution, suspension, emulsion; Eye drops, eye ointments, ointments, creams, suppositories.
- 2. Preparation of pharmacopoeal extracts and galenical products utilizing various methods of extraction.

### **Pharmacognosy**

Code:	PT 402
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

- 1. **Resins :** Study of Drugs Containing Resins and Resin Combination like Colophony, podophyllum, jalap, cannabis, capsicum, myrrh, asafoetida, balsam of tolu, balsam of peru, benzoin, turmeric, ginger.
- 2. Tanins : Study of tannins and tannin containing drugs like Gambir, gall and myrobalan.
- 3. **Volatile Oils :** General methods of obtaining volatile oils from plants; Study of volatile oils of Mentha, Cassia, Lemon peel, Orange peel, Lemon grass, Citronella, Caraway, Dill, Spearmint, Eucalyptus, Chenopodium, Valerian, Musk, Gaultheria, Sandal wood.
- 4. **Fibers :** Study of fibres used in pharmacy such as cotton, silk, wool, nylon, glass-wool, polyester and asbestos.

- 5. **Pharmaceutical aids :** Study of pharmaceutical aids like talc, diatomite, kaolin, bentonite, gelatine and natural colours.
- 6. Study of the biological sources, commercial varieties, chemical constituents, substitutes, adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following groups of drugs containing glycosides :
  - i) Saponins: Ginseng, dioscorea, sarsaparilla and senega
  - ii) Cardioactive sterols : squill, strophanthus and thervetia
  - iii) Anthraquinone cathartics : cascara
  - iv) **Others** : Psoralea, Ammi majus, Ammi visnaga, gentian, chirata, quassia.
- 7. Studies of traditional drugs, Common vernacular names, botanical sources, morphology, chemical nature of chief constituents, pharmacology, categories and common uses of following indigenous drugs :

Amla, Kantkari, Satavari, Tylophora, Bhilawa, Bach, Rasna, Punarnava, Chitrack, Apamarg, Gokhru, Shankhapushpi, Brahmi, Arjuna, Ashoka, Methi, Lahrun, Palash, Guggal, Gyumnema, Shilajit.

8. The holistic concept of drug administration in traditional systems of medicine, Introduction to ayurvbedic preprations like Aristha, Asvas, Gutikas, Tailas, Churnas, Lehyas, Bhasmas.

### Practical

Code:	PT 492
<b>Contacts:</b>	3
Credits: 2	

- 1. Microscopic study of powdered crude drugs containing volatile oil, glycosides, alkaloids etc.
- 2. Laboratory experiments on isolation, identification, separation and purification of various groups of constituents present in crude drugs of pharmaceutical significance.
- 3. Chemical tests for alkaloids, glycosides, steroids, flavonoids, tannins and resins etc.

### Pharmaceutical Chemistry (Bio-chemistry)

Code:	PT 404
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

- 1. Transport processes across cell membrane.
- 2. Production of ATP and its biological significance
- 3. Introduction to 3D structure of protein, stability and denaturation of protein, allosteric proteins.
- 4. **Enzymes :** Nomenclature, enzyme kinetics and its mechanism of action, mechanism of inhibition, enzymes and iso-enzymes in clinical diagnosis.
- 5. **Co-enzymes** : Vitamins as co-enzymes and their significance, Metals as co-enzymes and their significance.
- 6. **Carbohydrate Metabolism**: Conversion of polysaccharide to glucose 1 phosphate, Glycolysis and fermentation and their regulation, Gluconeogenesis and glycogenolysis, Metabolism of galactose and galactosemie, Role of sugar nuclectides in biosynthesis and Pentosephosphate pathway.
- 7. **The Citric Acid Cycle** : Significance, reactions and energetic of the cycle, Amphibolic role of the cycle, and Glyoxalic acid cycle.
- 8. **Lipids Metabolism** : Oxidation of fatty acids,  $\alpha$ -oxidation & energetic,  $\beta$ -oxidation,  $\omega$ -oxidation, Biosynthesis of ketone bodies and their utilization, Biosynthesis of saturated and unsaturated fatty acids, Control of lipid metabolism, Essential fatty acids & eicosanoids (prostaglandins, thromboxanes and leukotrienes) phospholipids, and sphingolipids.
- 9. **Biological Oxidation** : Redox-Potential, enzymes and co-enzymes involved in oxidation reduction & its control, The respiratory chain, its role in energy capture and its control, Energetic of oxidative

phosphorylation, Inhibitors of respiratory chain and oxidative phosphorylation, Mechanism of oxidative phosphorylation.

### Practical

Code: Contacts: Credits: 2	PT 494 3
1.	Experiments of sugar – test for reducing sugar, colorometric estimation of sugar, chromatographic separation of sugars.
2.	Titration curve for amino acids
3.	Separation of amino acids by TLC method.
4.	Experiments on lipids – saponification no., iodine no., separation of lipids by TLC.
5.	Quantitative estimation of amino acids, protein,
6.	Experiments on clinical bio-chemistry – blood glucose estimation, cholesterol in blood, separation of plasma proteins by paper electrophoresis, non-protein $N_2$ – in blood, estimation of SGOT, SGPT and ALP in the serum.
7.	Experiments on enzymes - effect of pH, effect of temperature and use of inhibitors.

#### **Physiology**

### Theory

Code:	PT 405
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

- 1. Nervous system, Central nervous system : Nerve impulse; Synapse Reflex arc, Receptor, organs, reflex action; Physiological mechanism governing the posture and equilibrium; The spinal cord and brain stem; The extra-pyramidal system, the thalamus and hypothalamus; Condition reflex, sleep; Cerebrum; cerebrospinal fluid.Autonomic nervous system : Classification, general arrangement, dual supply, drugs action on ANS, Structure of autonomic ganglia, general arrangement and function of Sympathetic and parasympathetic system.
- 2. Special sense : Taste (gustation). Smell (alfaction), vision and hearing
- 3. Body temperature and its regulation, pyrexia and hypotherms.
- 4. Reproductive system

### Pharmaceutical Engineering

Code:	PT 407
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

- 1. **Heat Transfer :** Heat transfer by conduction, problems on steady state heat conduction; heat transfer by convection, heat transfer coefficient, heat exchangers, problems on convection, heat transfer by radiation, Stefan's and Kirchoff's Laws, pharmaceutical applications.
- 2. **Evaporation :** Principles of evaporation, different evaporators like short and long tubes, forced convective and agitated film evaporators. Factors affecting evaporation rate. Multiple effect evaporation, pharmaceutical applications, Mathematical problems.

- 4. **Mixing :** Sampling and statistics of mixing, Different mixers: solid-solid, solid-liquid and liquidliquid, Problems of mixing and mixer selection.
- 5. **Crystallisation:** Introduction Crystal characteristics, solubility curves, supersaturation theory, nucleation, crystal growth etc., Industrial crystallisers like Swenson-Walker, tank type, agitated type and vacuum type etc. Different problems of crystallisation like caking etc.
- 6. **Materials of construction:** Introduction Corrosion, material properties, metals, non-metals and alloys for fabrication, specially stainless steel, aluminium, glass, polymers, rubber, ceramics and different Ni, Cr, Mn, Mo, Al, Fe, Si alloys. Different linings and surface coatings.

PracticalCode : PT 497Contacts :3 hrs./weekCredit :2

Practicals will be conducted as per the subject content in theory (at least 7 experiments)

### SEMESTER - V

Pharmaceutics (Pharmaceutical Technology-II)

Theory

Code:	PT 506
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

# 1. Tablets :

- a) Formulation of different types of tablets, granulation technology on large scale by various techniques, physics of tablets making, different types of tablet compression machinery and equipment employed, evaluation of tablet, Manufacturing area design and layout flow diagram of tablet manufacturing.
- b) Coating of tablets : Types of coating, sugar coating, film coating, film forming materials, formulation of coating solution, equipment for coating, coating process, evaluation of coated tablets, Physiological availability and tablet coating.
- c) Stability Kinetics and quality assurance.
- 2. **Capsules :** Advantages and disadvantages of capsule dosage form, material for production of hard gelatine capsules, size of capsules, method of capsule filling, sealing and packaging, Soft gelatine capsules shell and its content, important of base adsorption and factors, quality control, stability testing and storage.
- 3. **Cosmetology and Cosmetic preparation** : Fundamentals of cosmetic science, structure and function of skin and hair, formulation, preparation, packaging and evaluation of cosmetic products for skin, hair, eye, denitrifies and preparations like nail polish, lipstick; baby care products; shaving cream, after-shave lotions, etc.

Code:	PT 596
<b>Contacts:</b>	3
Credits: 2	

- 1. Formulation of various types of cosmetics for skin, hair, eye and different type of preparations.
- 2. Preparation, evaluation and packaging of tablets
- 3. Preparation, evaluation and packaging of hard gelatine capsules.

### Pharmacology

### Theory

Code:	PT 508
Contacts:	3L = 3
Credits: 3	

- 1. **General Pharmacology :** Introduction to Pharmacology, routes of drug administration, mechanism of action, Combined effect of drugs, Factors modifying drug action and related conditions.
- 2. **Fate of the drug and its administration,** Absorption, Distribution, Metabolism and Execration of drugs (ADME), Adverse Drug Reactions, drug interaction, Bio-transmission.
- 3. Pharmacology of Peripheral Nervous System :
  - a) Neurohumoral transmission (amines and related substance)
    - b) The choline esters and cholinesterase, Atropine and atropine like drugs, Drugs that block neuro-musculer or ganglionine transmission.
    - c) Neuromuscular blocking agents, Autogonists if adrenergic neurone activity, the cyclic neucleotides, 5-hydroxy tryptamide, histamine and its antagonist

### 4. Pharmacology of Central Nervous System :

- a) Neurohumoral transmission in the C.N.S.
- b) General Anaesthetics, local anaesthetics
- c) Alcohols and disulfiram
- d) Sedatives, hypnotics, Anti-anxiety agents
- e) Psychopharmacological agents: Anti-depressant, maniacs agents
- f) Anti-epileptics drugs
- g) Anti-Parkinsonian Drugs
- h) Analgesics, Antipyretics, Anti-inflammatory and Anti-gout drugs
- i) Narcotic analgesics and antagonists
- j) Drug-Addiction and Drug Abuse.
- 5. Screening and testing of drugs
- 6. Toxicity of drugs

#### Pharmaceutical Microbiology

Code:	PT 509
<b>Contacts:</b>	3L
Credits: 3	

- 1. Introduction to the scope of microbiology
- 2. Structure of bacterial cell.

3. Classification of microbes and their taxonomy. Actinomycetes bacteria, rickettsiae, spirochetes and viruses. 4. Identification of Microbes : Stains and types of staining techniques, electron microscope. 5. Nutrition, cultivation, isolation of bacteria, actinomycetes, fungi, viruses, etc. Control of microbes by physical and chemical methods. 6. Disinfection, factors influencing disinfectants, dynamics of disinfection, a) disinfectants and antiseptics and their evaluation. b) Sterilization, different methods, validation of sterilization methods & experiments. 7. Sterility testing of all Pharmaceutical products. Immunity, primary and secondary, defensive mechanisms of body, microbial resistance, interferon. 8. 9. Microbial assays of antibiotics, Vitamins (Vitamin B<sub>12</sub> & Niacin), amino acids. 10. Diseases and disease-producing microorganisms, like Staphylococcus aureus, Streptococcus pyrogenes, E. coli, Sulmonella typhi, Vibrio choleri and Yersinia pestis; virulence factors. 11. Water analysis by microbiological method 12. Pyrogen by LAL Test Practical

Code:	PT 599
<b>Contacts:</b>	3
Credits: 2	

Experiments devised to prepare various types of culture media, sub-culturing of common aerobic and anaerobic bacteria, fungus and yeast, various staining methods, various methods of isolation and identification of mircobes, sterilization techniques and their validation of sterilizing techniques, evaluation of antiseptics and disinfectants, testing the sterility of pharmaceutical products as per I.P. requirements, microbial assay of antibiotics and vitamins, water analysis.

### Pharmaceutical Chemistry (Medicinal Chemistry)

### Theory

Code:	PT 503
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

1<sup>st</sup> Half :

1. **Basic Principles of Medicinal Chemistry :** Physico-chemical aspects (Optical, geometric and bioisosterism) of drug molecules and biological action, Drug-receptor interaction including transduction mechanisms.

Synthetic procedures of selected drugs : Mode of action, uses, structure activity relationship including physico-chemical properties of the following classes of drugs :
 Drugs acting at Synaptic and neuro-effector junction sites :

- i) Cholinergics and Anti-cholinesterases
- ii) Adrenergic drugs
- iii) Antispasmodic and anti-ulcer drugs
- iv) Neuromuscular blocking agents.
- 3. Concept of QSAR and descriptors, statistical loop for QSAR, classical QSAR (Hansh and freewilson methods), CADD, Receptor based drug design like cyproheptadine HCL, paracetamol, diclofenac sodium, ibuprofen and analgin.
- 4. **Synthetic procedures of selected drugs :** Mode of action, uses, structure activity relationship including physicochemical properties of the following classes of drugs :

	<ul> <li>a) Autocoids         <ol> <li>Antihistamines</li> <li>Eicosancids</li> <li>Analgesic-antipyretics, anti-inflammatory (non-steroids) agents.</li> </ol> </li> <li>b) Drugs affecting uterine motility :         <ol> <li>Oxytocics (including oxytocin, ergot alkaloids and prostaglandins)</li> <li>Biochemical approaches in drug designing wherever applicable should be discussed.</li> </ol> </li> </ul>
Practicals	
Code: Contacts: Credits: 2	PT 593 3
1. 2. 3.	Synthesis of selected drugs from the course content (at least 3 experiments). Establishing the pharmacopoeial standards of the drugs synthesized. Special analysis of some selected drugs from the course content like cyproheptadine HCL, paracetamol, Diclofenac sodium, Ibuprofen and Analgin
Theory	Pharmaceutical Chemistry (Bio-chemistry )
Code: Contacts;	PT 504 3

# Credits: 3

- 1. **Hormones :** Pitutary gland, Thyroid gland and hormones secreted from pancreas
- 2. **Metabolism of Ammonia and Nitrogen Containing Monomers**: Nitrogen balance, bio-synthesis of amino acid, catabolism of amino acids (phenyl alamine methionine, histidime, alanine protein glycine) Conversion of amino acids to specialised products, Assimilation of ammonia, Urea cycle, metabolic disorders of urea cycle, Metabolism of sulphur containing amino acids, Porphyrin biosynthesis, formation of bile pigments, hyperbilirubinemia, Purine biosynthesis, Purine nucleotide interconversion, Pyrimidine biosynthesis, and Formation of deoxyribounucleotides.
- 3. **Biosynthesis of Nucleic Acids** : Brief introduction of genetic organization of the mammalian genome, alteration and rearrangements of genetic material, Biosynthesis of DNA and its replication, Mutation, Physical & chemical mutagenesis/carcinogenesis, DNA repair mechanism, Biosynthesis of RNA (Transcription) and Post transcriptional modifications.
- 4. Vitamines : Water and fat soluble vitamines
- 5. **Genetic Code and Protein Synthesis** : Genetic code, Components of protein synthesis, and Inhibition of protein synthesis, post translational modifications and distribution of protein of different organelles, Brief account of genetic engineering and polymerase chain reactions.
- 6. **Regulation of gene expression**.

# Pharmaceutical Engineering

Code:	PT 507
<b>Contacts:</b>	3
Credits: 3	

- 1. **Molecular Diffusion and Interphase Mass Transfer**: Molecular diffusion in gas and liquid systems. Introduction to interphase mass-transfer, mathematical problems
- 2. **Distillation**: Batch distillation, rectification of binary mixtures, bubble cap, sieve phate and packed bed columns, design method of plate co,umns, steam, vacuum, molecular and azeotropic distillations, problems (Mathematical problems)
- 3. **Extraction**: Solvent extraction (liquid-liquid) and leaching, parallel current and cross-treatment method, equipments like batch extractor, centrifugal extrictor, continuous leacher etc. problems (mathematical problems)
- 4. **Drying :** Mechanism of drying, theory of drying, concept of EMC, CMC, FMC, drying rate curves, drying problems, pharmaceutical dryers like tray, vacuum, rotary, fluidized-bed, pneumatic, spray, freeze and infrared dryers, mathematical problems.
- 5. **Humidification and Refrigeration:** Dry and wet bulb thermometry, Psychometirc chart, humidity measurement, Equipments for humidification and dehumidification, pharmaceutical application and mathematical problems, principles of refrigeration, units of refrigeration, refrigerants, application in pharmacy.
- 6. **Process control system:** Basic instrumentation and control in pharmaceutical industries, measurement of temperature, pressure, flow rate, humidity, vacuum and level by automatic process control systems.

### Practical

Code:	PT 597
<b>Contacts:</b>	3P
Credits: 2	

- 1. Measurement of flow of fluids and their pressure, determination of Reynold's number and calculation of Frictional losses.
- 2. Evaluation of filter media, determination of rate of filtration and study of factors affecting filtration.
- 3. Determination of humidity use of Dry Bulb and Wet Bulb.
- 4. Determination of overall heat transfer co-efficient.
- 5. Determination of rate of evaporation.
- 6. Determination of rate of drying, free moisture content and bound moisture content.
- 7. Experiments to illustrate principles of size reduction, Laws governing energy and power requirements of size Reduction.
- 8. Experiments on batch distillation and to verify Reileigh's equation, study of the performance of different dryers.

### SEMESTER - VI

### Pharmaceutical Chemistry (Medicinal Chemistry)

# Theory

Code:	PT 603
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

Synthetic procedures of selected drugs, mode of action, uses, structure activity relationship including Physico-Chemical properties of the following classes of drugs :

- **1. Drugs acting on the Central Nervous System :** General Anesthetics, Local Anesthetics, Hypnotics and Sedatives, anti-convulsants, Antiparkinsonism drugs, Antipsychotic, antidepresants,
- 2. **Diuretics, Cardiovascular drugs** (anti-anginal, antirrhythmic, antihypertensive, anticoagulant. Anti-platelet and antihyperlipidemics

- 3. **Steroids and related drugs :** Steroidal nomenclature and stereochemistry, androgens and anbolic agents, estrogens and progestational agents, adrenocorticoids.
- 4. **Alnatoids** Definition, general identification test, determination of functional group and structure elucidation of Atropin and Ephidrine

### Practical

Code:	PT 693
<b>Contacts:</b>	3
Credits: 2	

- 1. Workshop on stereomodel use of some selected drugs.
- 2. Synthesis and identification of selected compounds from the course content (Benzil, Benzillicacid, Diphenyl hydantoin, Benzocaine ).
- 3. Assay of some selected drug formulation from the course content (Propranolol HCL, warfarin sodium, verapamil hydrochloride, chlordiazepoxide, spironolactone, diazepam) (any four).

# Pharmaceutics (Pharmaceutical Technology)

### Theory

Code:PT 606Contacts:3Credits: 3

### 1. **Parenteral Products :**

- a) Pre-formulation factors, routes of administration, water for injection, pyrogenicity, nonaqueous vehicle, isotonicity and methods of its adjustment.
- b) Formulation details; containers, closures and their selections.
- c) Pre-filling treatment, washing of containers and closures, preparation of solution and suspension, filling and closing of ampoules, vials, infusion fluids, lyophillization and preparation of sterile powders, equipment for large scale manufacture and evaluation of parenteral products.
- d) Aseptic Techniques : source of contamination and methods of prevention, design of aseptic area, laminar flow bench services and maintenance.
- e) Sterility testing of pharmaceuticals.
- 2. **Surgical Products :** Definition, primary wound dressing, absorbents, surgical cotton, surgical gauze etc., bandages, adhesive tape, protective cellulosic hemostatics, official dressing, absorbable and non-absorbable sutures, ligatures and catguts, preparation and sterilization of surgical catguts.
- 3. **Packaging of Pharmaceutical Products :** Packaging components, types, specifications and methods of evaluation, stability aspect of packaging, packaging equipment, factors influencing choice of containers, legal and other official requirements for containers, packaging testing.
- 4. **Novel drug delivery system :** Introduction to novel drug delivery systems like micro-capsule and micro-pellet parenteral and implantable therapeutic systems, transdermal therapeutic systems, micro-particulate drug carrier system, micro-encapsulation types, method of preparation and evaluation.

### Practical

Code:PT 696Contacts:3Credits: 2

- 1. Preparation of a sustained release oral dosage form and its evaluation
- 2. Evaluation of materials used in pharmaceutical packaging.
- 3. Paraffin gauge dressings.

### Pharmaceutics (Biopharmaceutics and Pharmacokinetics)

### Theory

Code:	PT 611
<b>Contacts:</b>	3L + 1T = 4
Credits: 4	

1. Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting.

### 2. **Biopharmaceutics** :

2.1 Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis)

- 2.2 Factors influencing absorption-Physicochemical, physiological and pharmaceutical.
- 2.3 Drug distribution in the body, plasma protein binding.

# 3. **Bioavailability and bioequivalence** :

- a) Measures of bioavailability,  $C_{max}$ ,  $t_{max}$  and area under the curve (AUC).
- b) Design of single dose bio-equivalence study and relevant statistics.
- c) Review of regulatory requirements for conduction of bio-equivalent studies.

# 4) **Pharmacokinetics** :

- a) Significance of plasma drug concentration measurement
- b) Compartment model-Definition and Scope
- c) Pharmacokinetics of drug absorption-Zero order and first order absorption rate constant using Wagner Nelson and Loo-Reigelman method.
- d) Volume of distribution and distribution coefficient.
- e) Compartment kinetics-One compartment and two compartment models. Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intravascular and oral route.
- f) Curve fitting(method of Residuals), regression procedures.
- g) Clearance concept, Mechanism of renal clearance, clearance ratio, determination of renal clearance.
- h) Extraction ratio, hepatic clearance, biliary excretion, Extrahepatic circulation.
- i) Non-linear pharmacokinetics with special reference to one compartment model after I.V. drug administration, Michaeles Menten Equation, detection of non-linearity (Saturation mechanism).

# 5. Clinical Pharmacokinetics :

- a) Definition and scope
- b) Dosage adjustment in patients with and without renal and hepatic failure.
- c) Design of single dose bio-equivalence study and relevant statistics.
- d) Pharmacokinetic drug interactions and their significance in combination therapy.

### Practical

Code: PT 697 Contacts: 3P Credits: 2

- 1. Analysis of biological specifications for drug content and estimation of the pharmacokimetic parameters.
- 2. In vitro evaluation of different dosage forms for drug release.
- 3. Absorption studies in vitro
- 4. Statistical treatment of pharmaceutical data.

### Pharmacology

### Theory

Code:	PT 608
<b>Contacts:</b>	3
Credits: 3	

### 1. Pharmacology of Cardiovascular System :

- a) Digitalis and cardiac glycosides
- b) Antihypertensive drugs
- c) Anti-anginal and Vasodilator drugs
- d) Anti-arrhythmic drugs
- e) Anti-hyperlipedemic drugs
- f) Drugs used in the therapy of shock

# 2. Drugs Acting on the Hemopoetic System :

- a) Hematinics
- b) Anticoagulants, Vitamin K and hemostatic agents.
- c) Fibrinolytic and anti-platelet drugs
- 3. **Bioassay**: Definition; merits and demerits threshold dose bracketing, four point and other assay; bioassay of acetylcholine, hydroxytryptamine, adrenaline, noradrenaline, sedative agents, oxytocin, digitalis, different hormones, local anesthetics, etc.

# 4. **Drugs acting on urinary system :**

- a) Fluid and electrolyte balance
- b) Diuretics

### 5. **Autocoids :**

- a) Histamine, 5-HT and their antagonists
- b) Prostaglandins, thromboxanes and leukotrienes

# 6. **Drugs Acting on the Respiratory System :**

- a) Anti-asthmatic drugs including bronchodilators
- b) Anti-tussives and expectorants

### Practical

Code:	PT 698
<b>Contacts:</b>	3
Credits: 2	

1.	Experiments on intact preparations :	
	Study of different routes of administration of drugs in mice/rats.	
2.	Experiments on Central Nervous system :	

- **Experiments on Central Nervous system :** Recording of spontaneous motor activity, stereotype, analgesia, anticonvulsant activity, and inflammatory activity and muscle relaxant activity of drugs using simple experiments.
- 3. Effects of autonomic drugs on rabbit's eye :

4. Effects of various agonists and antagonists and their characterization using isolated preparations like frog's rectus abdominis muscle and isolated ileum preparations of rat guinea pig and rabbit.

# 5. **Experiments on Isolated Preparations : ( at least three)**

- a) To record the concentration response curve (CRC) of acetylcholine using rectus abdominis muscle preparation of frog.
- b) To study the effects of physostigmine and d-tubocurarin on the CRC of acetylcholine using rectus abdominis muscle preparation of frog.
- c) To record the CRC of 5-HT on rat uterus preparation.
- d) To record the CRC of histamine on guineapig ileum preparation
- e) To record the CRC of noraderenaline on rat anococcygeus muscle preparation.
- f) To record the CRC of oxytocin using rat uterus preparation

# 6. **Abnormal toxicity test (Phenol)**

# Pharmaceutical Biotechnology & Industrial Microbiology

### Theory

Code:	PT 609
<b>Contacts:</b>	3
Credits: 3	

- 1. **Immunology and Immunological Preparations :** Principles, antigens and Haptens, Immune system, cellular humoral immunity, immunological tolerance, antigen-antibody reactions and their applications. Hypersensitivity, active and passive immunization, Vaccines – preparation, standardization and storage.
- 2. Genetic Recombination : Microbialgenetics & variation, Transformation, conjugation, transduction, protoplast fusion and gene cloning and their applications, Development of hybridoma for monoclonal antibodies, Study of drugs produced by biotechnology such as Activase, Humulin, Humatrope, HB etc
- 3. **Antibiotics :** Historical development of antibiotics, Antimicrobial spectrum and methods used for their standardization, Screening of soil for organisms producing antibiotics, fermenter, its design, control of different parameters. Isolation of mutants, factors influencing rate of mutation. Design of fermentation process. Isolation of fermentation products with special reference to penecillins, streptomycins tetracyclines and vitamin B12.
- 4. **Microbial Transformation :** Introduction, types of reactions mediated by microorganisms, design of biotransformation processes, selection of organisms, biotransformation process and its improvements with special reference to steroids.
- 5. **Enzyme immobilization :** Techniques of immobilization of enzymes, factors affecting enzyme kinetics. Study of enzymes such as hyaluronidnse, penicillinase, streptokinase and streptodornase, amylases and proteases etc. Immobilization of bacteria and plant cells.
- 6. Fermentative Production of alcohol

# Elective-I

Theory		
Code:	:	
Contac	ts:	
Credits	:3	

3L

Students may opt any one of the following subjects :

- 1. PT610A: Computer Application in Pharmaceutical Technology and in Clinical Pharmacy
- 2. PT610B: Advanced Pharmaceutical Biotechnology

### SEMESTER - VI

### Pharmaceutics (Pharmaceutical Technology) Theory

Code:	PT706
<b>Contacts:</b>	3
Credits: 3	

1. **Preformulation studies :** 

- a) Introduction, qualification of preformulators, microscopy, thermal analysis, x-ray polymorphism, hygroscopicity, density, powder flow, solubility, Pka, P-C dissolution.
- b) Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc. and their influence on formulation and stability of products.
- c) Study of pro-drugs in solving problems related to stability bio-availability and elegancy of formulations.
- 2. Design, development and process validation methods for pharmaceutical operations involved in the production of pharmaceutical products with special reference to tablets, suspensions.
- 3. Stabilization and stability testing protocol for various pharmaceutical products.

### 4. **Performance evaluation methods** :

In vitro dissolution studies for solid dosage forms method interpretation of dissolution data.

- 5. GMP and quality assurance, Quality audit.
- 6. Principle, production and evaluation of oral controlled released formulations.

### Practical

Code:	PT 796
<b>Contacts:</b>	3
Credits: 2	

- 1. Dissolution testing and data evaluation for oral solid dosage forms.
- 2. Design, development and evaluation of controlled release formulations.

Note: At least seven experiments to be performed

### Pharmaceutical Chemistry (Medicinal Chemistry-III)

### Theory

Code: PT 703 Contacts: 3 Credits: 3

Structure, Synthetic procedures uses of the selected drugs and mode of action of the following classes of drugs :- ,

	<ol> <li>Anti-biotics &amp; Chemotherapeutic agents : β-lactam, chloramphenicol, macrolides, aminoglycosides, Macrolides, Chloramphenicol, Anthelmintic Fluoroquinolones, Antiviral, antimalarial, Antifungal, Antimaoebic, Antileprotic and Antitubercular drugs).</li> <li>Antineoplastic agents</li> </ol>	
	<ol> <li>Thyroid and anti-thyroid drugs</li> <li>Insulin and oral hypoglycaemic agents</li> </ol>	
Practical		
Code: Contacts: Credits: 2	PT 793 3P	
	<ol> <li>Synthesis of any three selected drugs (e.g. sulphacetamide, ethambutol, PABA, Isonicotinic acid etc.,)</li> <li>Pharmacopoeial assay of any four selected drugs (any three) formulations (Chlorpropamide, Albendazole, Metformin HCL, Rifampicin, Trimethoprim)</li> </ol>	
Theory	Pharmacognosy	
Code: Contacts: Credits: 3	PT 702 3	
1.	Biogenesis and pharmacological activity of medicinally important monoterpenes, sesquiterpenes, diterpenes and triterpenoids.	
2.	<b>Carotenoids</b> : $\alpha$ -carotenoids, $\beta$ -carotinoids, Vitamin A, Xanthophylls of medicinal important.	
3.	<b>Glycosides</b> : Chemistry and bio-synthesis of digitoxin, digoxin, hecogenin, sennosides, diosgenin and sarasapogenin.	
4.	<b>Alkaloids</b> : Chemistry, biogenesis and pharmacological activity of atropine and related compounds; quinine, reserpine, morphine, papaverine, ephedrine, ergot and vinca alkaloids, general method for isolation of alkaloids.	
5.	Historical development of plant tissue culture, types of cultures, nutritional requirements, growth and their maintenance, Applications of plant tissue culture in pharmacognosy.	
6.	Marine pharmacognosy, novel medicinal agents from marine sources.	
7.	Cultivation, collection, identification, preservation of important medicinal plants and herbs	
8.	Screening of flavonoids and polyphenols in plant extracts.	
	Basic metabolic pathways and biogenetics of secondary metabolites of pharmaceutical importance.	
9.	Basic metabolic pathways and biogenetics of secondary metabolites of pharmaceutical importance.	

# Pharmacology

# Theory

Code:PT 708Contacts:3Credits: 3

#### 40

### 1. **Pharmacology of Endocrine System :**

- a) Hypothalamic and pituitary hormones
- b) Thyroid hormones and anti-thyroid drugs, calcitonin.
- c) Insulin, oral hypoglycaemic agents & glucagon
- d) ACTH and corticosteroids
- e) Androgens and anabolic steroids
- f) Estrogens, progesterone and oral contraceptives.
- g) Drugs acting on the uterus.

# 2. Chemotherapy;

- a) General Principles of Chemotherapy
- b) Sulfonamides and cotrimoxazole
- c) Antibiotics-Penicillins, Cephalosporins, Chloramphenicol, Etythromycin, Quinolones and Miscellaneous Antibiotics.
- d) Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases.
- e) Chemotherapy of malignancy and Immunosuppressive Agents

### 3. Drugs Acting on the Gastrointestinal Tract :

- a) Antacids, Anti Secretory and Anti-ulcer drugs
- b) Laxatives and anti-diarrhoeal drugs.
- c) Emetics and anti-emetics

### Elective -II

Code: Contacts: 3 Credits: 3

Students may opt any one of the following subjects :

- 1. PT709A: Packaging Technology
- 2. PT709B: Advanced Pharmacognosy
- 3. PT709C: Pharmaceutical Marketing Management

#### Project

Code: PT 783 Contacts: 8 Credits: 6 SEMESTER – VIII

**Pharmaceutical Industrial Management** 

Theroy	
Code:	PT 812
<b>Contacts:</b>	3
Credits: 3	

- 1. **Concept of Management :** Administrative Management (Planning, Organizing, Staffing, Directing and Controlling), Entrepreneurship development, Operative Management (Personnel, Materials, Production, Financial, Marketing, Time/space, Margin/Morale). Principles of Management (Co-ordination, Communication, Motivation, Decision-making, leadership, Innovation, Creativity, Delegation of Authority/Responsibility, Record Keeping). Identification of Key points to give maximum thrust for development and perfection.
- 2. Accountancy : Principles of Accountancy, Ledger posting and book entries, preparation of trial balance, columns of a cash book, Bank reconciliation statement, rectification of errors, Profits and

loss account, balance sheet, purchase, keeping and pricing of stocks, treatment of cheques, bills of exchange, promissory notes and hundies, documentary bills.

- 3. **Economics :** Principles of economics with special reference to the laws of demand and supply, demand schedule, demand curves, labour welfare, general principles of insurance and inland and foreign trade, procedure of exporting and importing goods.
- 3. **Pharmaceutical Marketing :** Functions, buying, selling, transportation, storage, finance, feedback, information, channels of distribution, wholesale, retail, departmental store, multiple shop and mail order business.
- 5. **Salesmanship :** Principles of sales promotion, advertising, ethics of sales, merchandising, literature, detailing, Recruitment, training, evaluation, compensation to the pharmacist.

# 7. Market Research :

- a) Measuring & Forecasting, Market Demands, Major conception, demand measurement, Estimating current demand, Geo-demographic analysis, Estimating industry sales, Market share & Future demand.
- b) Market Segmentation & Market Targeting.
- 8. **Materials Management :** A brief exposure or basic principles of materials management-major areas, scope, purchase, stores, inventory control, an evaluation of material management.
- 9. **Production Management :** A brief exposure of the different aspects or Production, Management-Visible and Invisible inputs, Methodology of Activities. Performance Evaluation Technique, Process-Flow, Process Know-how, Maintenance Management.
- 10. Personal Management
- 11. Concept of GLP, ISO 9000 and TQM

# **Pharmaceutical Jurisprudence & Ethics**

### Theory

Code: Contacts: Credits: 3	PT 813 3	
1.	Introduction	
	Pharmaceutical legislation – A brief review.	
2.	An elaborate (practical oriented) study of the following	
	a) Pharmaceutical Ethics	
	b) Pharmacy Act 1948	
	c) Drugs and Cosmetics Act 1940 and Rules 1945	
3.	An elaborate (practical oriented) study of the following	
	d) Medicinal & Toilet Preparations(Excise Duties) Act 1955	
	e) Narcotic Drugs & Psychotropic Substances Act 1955 & Rules	
	f) Drugs Price Control Order.	
4.	A brief study of the following with special reference to the main provisions.	
	a) Drugs and Magic Remedies(Object Advertisements Act 1954)	
	b) Medical Termination of Pregnancy Act 1970 & Rules 1975.	
	c) Prevention of Cruelty to Animals Act 1960.	
	d) States Shops & Establishments Act & Rules.	
	e) Factories Act 1948.	
	f) Patents Act (latest)	

# Note: The teaching of all the above Acts should cover the latest amendments.

Hospital & Clinical Pharmacy		
Theory Code: Contacts: Credits:3	PT 818 3	
Ci cuits.e	Hospital pharmacy :	
1.	Organisation and Structure : Organisation of hospital pharmacy, Responsibilities of a	
2.	hospital pharmacist, Pharmacy and therapeutic committee. <b>Hospital Formulary</b> : Contents, preparation and revision of hospital formulary.	
3.	Drug distribution Systems in Hospitals :	
	<ul> <li>a) Out-patient dispensing, methods adopted.</li> <li>b) Dispensing of drugs to in-patients. Types of drug distribution systems, Charging policy, labelling.</li> </ul>	
4.	<b>Manufacture of Sterile and Nonsterile Products :</b> Policy making of manufacturable items, demand and costing, personnel requirements, manufacturing practice. Master formula Card, production control, Manufacturing records.	
	Clinical Pharmacy	
1. 2.	Introduction to Clinical Pharmacy. Important Disorders of Organ Systems and their Management :	
۷.	a) Cardiovascular Disorders-Hypertension, Congestive Heart Failure, Angina, Acute	
	<ul><li>Myocardial Infraction, Cardiac arrhythmia.</li><li>b) CNS Disorders : Epilepsy, Parkinsonism, Schizophrenia, Depression.</li></ul>	
3.	Basic Concepts of Pharmacotherapy.	
	<ul><li>a) Drug use during Pregnancy</li><li>b) The Basics of Drug Interactions, types of drug-drug interaction, pharmacokinetic and</li></ul>	
4.	pharmacodynamic drug interaction, drug-food interaction.	
5.	Basic concepts of Clinical trials – Phase-I, Phase-II, Phase-III & IV	
6.	6. Basic concept of Clinical trial monitoring	
Theory	Pharmaceutical Analysis	
Code:	PT 801	
Contacts: Credits: 3	3	
	theoretical aspects, basic instrumentation, elements of interpretation of spectra and applications of the owing analytical techniques would be discussed :	
	1. Ultraviolet and visible spectrophotometry	
	<ol> <li>Fluorimetry</li> <li>Infrared spectrophotometry(FT-IR – an introduction)</li> </ol>	
	4. Flame Photometry	
	5. Nuclear Magnetic Resonance Spectroscopy	

Nuclear Magnetic Resonance Spectroscopy 5.

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- 6. 7. Mass-spectrometry Atomic Absorption spectroscopy

8. Radio immunoassay

Practical

Code:	PT 891
<b>Contacts:</b>	3
Credits: 2	

- Quantitative estimation as per pharmacopoeial method of at least seven formulations containing 1. single drug or more than one drug, using instrumental techniques 2.
  - Estimation of Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup> ions using flame photometry.

# **ELECTIVE SUBJECTS**

# **SEMESTER-VI**

### Elective - I Computer application in Pharmaceutical Technology Paper Code :PT 610A

3 hr / week

Relational Database and SQL

Introduction to data base, DBMS. Database versus early file keeping system, need for DBMS, Database Languages, users and administrators, Database architecture, types of databases. Integrity-: domain constraints and referential integrity Introduction to Relational Database, tables and fields, Relational databses design : Functional Dependencies, decomposition, 1NF, 2NF, 3NF, and BCNF Structured Query Language (SQL)

#### 1. Statistical analysis using standard package

Linear Regression and Correlation: Introduction, Fitting lines, confidence label, Analysis of residuals, nonlinear regression. Studies of this parameter through computer package.

- 2) Computer aided drug design:- A preliminary approach to QSAR and combinatorial chemistry,
- 3) Use of database management system (DBMS) in clinical drug interaction and drug information services.

### Practical

Computer application in Pharmaceutical Technology

Paper Code :PT 691A	,
Contact : 3	
Credit : 2	

### Exercise based on topics like :

- 1. Creating and modifying table with Oracle, querying with SQL
- Quantitative structure activity relationship 2.
- 3. Data base system and use of this system using FOXPRO or Microsoft Access in clinical drug interaction and drug information services

### Advanced Bio-technology [ PT 610 B ]

# 1. Introduction & historical background

- a) Scientific & Technological foundations
- b) Micro & nano-technology for medicine

# 2. Bio-technology & Medicines

- a) Vitamins b) Steroids
- c) Amino acid d) Proteins
- e) Antibiotics f) Natural compounds
- a) Gene farming
  - i) Animals
  - i) Plants

# 3. Recombinant DNA Technology

- a) Concept
- b) Cutting and rejoining of DNA
- c) DNA segregating
- d) PCR in gene amplification
- e) Isolation and amplification of gene

### 4. **Bio-informatics**

a) Molecular pharmaceutical biotechnology Moral and ethical questions (safety – medical, biological, chemical)

# PRACTICAL [ PT 691B ]

- 1. Protein separation by gel eletrophoresis
  - a) Assembling of Electrophoresis apparatus
  - b) Gel casting
  - c) Loading of proteins in the gel and separation according to molecular weight
  - d) Staining of protein bands in the gel.
- 2. Microtechnique : Preparation of animal tissue sections for histological / histopathological / immunocytochemical studies
- 3. Estimation of hormone concentration from blood serum by immunoassays like ELISA
- 5. Extraction of (a) total RNA

(b) DNA ] from tissue extracts

- (c) Protein ]
- 6. Spectrophotometric assay of enzymes
- 7. Estimation of
  - (a) Serum Glutamate Oxaloacetate Transaminase (SGOT) Test
  - (b) Serum Glutamate Pyruvate Transaminase (SGPT) Test
  - (c) Protein with standard curve by Ninhydrine method

# **SEMESTER-VII**

### Packaging Technology (Elective –II)

Code:		(PT 709A)
Contact		3
Credit	:	3
1.		Packaging of pharmaceutical dosage form
	a.	Introduction, Definition and function, regulatory requirement, Nature of package evaluation
	b.	Packaging of solid oral dosage form : scope, Packaging, stability and shelf life containers and
		Closures, Unit dosage packaging.
	c.	Packaging of parenteral and ophthalmic: scope, regulatory requirements, containers, Closures.
	d.	Packaging of semisolids and topicals: scope, Closures and containers for different liquid and
		semisolid formulations, transdermal devices.
	e.	Packaging of aerosols: scope, pressurized containers, metered dose inhalers, non- pressurized
		containers, spray pumps, drug powder inhalers.
	f.	Influence of packaging components on dosage form stability.
1.		Packaging materials science
	a.	Glass packaging materials - containers and Closures
		Glass as a packaging material, composition, types, manufacture of glass.
	b.	Plastic packaging materials - containers and Closures
		Introduction, methods of preparation, classification of materials, Drug-plastic considerations,
		Selection of proper materials, drug plastic considerations, selection of proper materials.
	c.	Metal packaging materials - containers and Closures
		Introduction, Modern packaging metal, Tinplate and associated materials aluminum, Types of metal containers.
		containers.
2.	Tamper	– Resistant packaging
	1 unip 01	Introduction, Film Wrapper, Blister package, strip package, Bubble pack, Shrink bonding, foil,
		paper of plastic pouches, bottle seals, tape seals, breakable caps, sealed tubes, aerosol containers,
		sealed containers.
3.	Quality	control and storage of packaging materials.
		ng packages for disposability (Wastage control)
	-	

# Pharmaceutical Marketing Management (Elective-II)

Code:	[ 709 C ]
<b>Contact :</b>	3 hrs. / week
Credit :	3

Understanding of Pharmaceutical Marketing Management Defining Marketing

- ii) Marketing Task Demand States & Marketing task, Scope of Marketing, Different Markets.
- iii) Concept of Marketing Definition of marketing, Distinction between marketing & Selling, Core Marketing Concept, Marketing Place, Marketing Space, Target Market, Segmentation of Market, Needs, wants & Demands, Product offering, value & satisfaction, Relationship net work, Supply chain competition, Marketing Environment, Marketing Mix (4 P Components), Other concept's name under marketing activities.

### **Marketing Opportunities**

- 1) Market Oriented Strategic Planning SWOT Analysis, Stragic Formulation, Product Planning,
- Gathering Information & Measuring Demand MIS, Market Research, Behavioural Research, Marketing Research, Forecasting & Demand Measurement.
- 3) Analysing Consumer Markets & Buyer Behaviour Influencing Buyer Behaviour, Buying Decision Process, Motivation of Physician towards Brand.
- 4) Dealing With the Competition Identifying Competitors, Analysing Competitors, Strategies, Strength & Weakness. Designing Competitive Strategies.

### Developing Market Strategies & Marketing Mix, Product Strategy

- 1) Positioning & Differentiating the Market Offering (Product) Positioning to Promote,
- 2) Product Life Cycle marketing Strategies- Product Life Cycle
- 3) New Market Offering Which markets to Enter, How to Enter the Market, Product Development, Market Testing.

4) Setting the Product Strategy – Product & Product Mix., Product Line analysis, Brand Decision, Packaging & Labeling.

#### Managing & Delivering Marketing Programs

- Value Net- Work & Marketing Channels Channel Functions, Channel Levels, Channel Management, Decisions, Selecting, Training, Motivating & Evaluating Channels Members, Channel Dynamics, Conflicts, Co- operation & Competitions.
- Managing Retailing, Wholesaling & Market Logistics Types of Retailing, Types of Wholesaling.
- Managing Advertising, Sales Promotion & Public Relations Advertising Objective, Choosing the Advertising Message, Measuring Effectiveness of Advertisement. Sales Promotion & Purpose, Public Relations.
- 4) Managing Sales Force- Recruitment & Selecting Representative, Training sales Representative, Supervising, Norms for Customer Calls, Motivating Sales representative, Evaluating Sales representative.

### Elective - II Advanced Pharmacognosy

Paper code : 709B Contact - 3 period / week Credit : 3

- 1. Indigenous systems of medicines with emphasis on Ayurveda.
- 2. Some important techniques associated with quality control of Herbal Drugs :
  - a. Adulteration & deterioration
  - b. Factors affecting Herbs quality
  - c. TLC / HPTLC
  - d. Sampling procedures
  - e. Morphological examination
  - f. Microscopical evaluation
  - g. Chemical evaluation

- 3. Pharmacological Screening of herbal drugs.
- 4. Quality assurance & stability testing of herbal drugs.
- 5. Extracrion of herbal drugs
  - a. Basic principle
  - b. Preextraction operation for crude drugs
  - c. Effect of solvent, solvent mixture & solution of extraction
  - d. Procedure of extraction
  - e) Treatment of dry residue after extraction

### **INSTRUCTIONS**

- 1. Each Semester will consist of a minimum of 15 weeks instructions :
- 2. Internal assessment of Theoreticals (30%) will be based on two class tests of 10 marks in each of the theory subject during each semester and 10 marks for class attendance of student in each subject.
- 3. Internal assessment of practicals (40%) will be based on day to day attendance, viva, laboratory record etc. There will be no separate class test in practicals. The choice in question papers shall be restricted to 25% only. Complete coverage of prescribed syllabus in university question papers is desired.
- 4. A minimum of 75% attendance in theory and practical classes is compulsory.
- 5. In view of the fact that B. Pharm is a professional degree course with diverse employment potential, the university degree certificate may continue to remain the same with no mention of elective subjects. However, the mark-list should indicate the elective(s) opted by the candidate.
- 6. Pass mark in both theory and practical papers is as per WBUT norms.
- 7. Pass mark in aggregate will be as per W.B.U.T. norms.
- 8. Class / Division awarded to the student will be decided as per WBUT norms.
- 9. Student has to clear back paper(s), if any, of 1<sup>st</sup> and 2<sup>nd</sup> Semester before appearing in the 5<sup>th</sup> Semester Examination and the same of 3<sup>rd</sup> and 4<sup>th</sup> Semester before appearing in the 7<sup>th</sup> Semester Examination.
- 10. A student will get a maximum of 8 yrs. time from the date of admission to complete the degree course.
- 11. Practical examination is essential as per PCI norms :
  - iii) Sessional : 40
  - iv) Practical examination : 60
- 12. Presence of External Examiner in Practical examinations is mandatory.

# STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR MASTER DEGREE IN PHARMACEUTICAL TEHCOLOGY ( M. PHARMA ) IN PHARMACEUTICS

# SEMESTER-I

		A. <u>THI</u>	EORY					
SL. NO.	CODE	THEORY		CONTACTS (PERIODS/WEEK)				CREDITS
				L	Т	P	TOTAL	
01	MPT-106	Dosage form design parameters & pharmaceutical product development		4				3
02	MBS-101	Bio-Statistics (Common paper)		4				2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)		4				3
04	MPT-116	Bio-pahramceutics & pharmacokinet	ics	3				2
	1	Sessi	onal		1		11	
05	MPT-181	Seminar						1
06	MPT-196	Pharmaceutical Technology Lab.				4		3
	MPT-191	Pharmaceutical Analysis Lab.				4		3
								17
FULL	MARKS FOR	PAPER WITH 2 / 3 CREDIT POINT	=	100				
FULL	MARKS FOR	PAPER WITH 1 CREDIT POINT	=	50				
FULL	MARKS FOR	PAPER WITH 5 CREDIT POINT	=	200				
FULL	MARKS FOR	PAPER WITH 9 CREDIT POINT	=	300				

SEMISTER-II

		A. <u>THEORY</u>					
SL. NO.	CODE	THEORY			NTAC ODS/V	CTS WEEK)	CREDITS
			L	Т	Р	TOTAL	
01	MPT- 206(1)	Drug Delivery System	3				2
02	MPT-209	Pharmaceutical Bio-technology	4				3
03	MPT-212	Process validation & CGMP (Common paper)	4				3
04	MPT- 206(2)	Physical Pharmaceutics	2				1
		Sessional					
05	MPT-281	Seminar					1
06	MPT-296	Bio-pharmaceutics Lab.			4		2
							13

# SEMISTER-III

	A. <u>THEORY</u>						
SL. NO.	CODE	THEORY			NTA ODS/	CTS VEEK)	CREDITS
NO.			L	T	P	TOTAL	
01	MPT-314	Research Method & Clinical Trials	3				2
02	MPT-391	Synopsis					5
03	MPT-392	Presentation					3
							10

# SEMISTER-IV

SL. NO.	CODE	THEORY			CTS WEEK)	CREDITS	
			L	Т	Р	TOTAL	
01	MPT-496	Thesis					9
02	MPT- 496(1)	Defence of Thesis					3
							12
in pre	sence of Ext	presentation of 1 <sup>st</sup> semester and Thesis and Defe ernal Examiner(s). The Final Credit should be e internal and external examiners.					

### SYLLABUS FOR M. PHARM IN PHARMACEUTICS

### **SEMESTER-I**

# DOSAGE FORM DESIGN PARAMETERS & DEVELOPMENT OF PHARMACEUTICAL PRODUCT

Code: MPT-106 Contact: 4L Credits: 3 Full marks: 100

- A] 1. Physicochemical aspects
  - a) pKa
  - b) Partition Coefficient
  - c) Solubility
  - d) Solid state characterization and physical behaviour of drugs
  - e) Reaction kinetics and mechanisms

### 2. Biological aspects

- a) Role of physicochemical parameters on drug absorption and their implications.
- b) Routes of administrations and implication on bio-availability.
- c) Physicochemical aspects of drugs and first pass metabolism.
- B] 1. Pre-formulation studies :

Preformulation testing, preformulation trials, in-vitro and in-vivo trials, preformulation worksheet

- 2. Stages in product development and evaluation, product development functions, Data required for product development, formulation factors.
- 3. Pilot Plant Scale up. Importance and technique involved.

### **Bio-Statistics**

Code : MBS-101 Contact : 4L Credits: 2

# Full marks : 100

1. An introduction to statistics and bio-statistics collection and organisation of data: Graphical and pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, coefficient of variation, mean error, relative error, precision and accuracy.

- 2. *Probability:* Definition and probability distributions, normal, binominal and polynominal distributions, continuous data distribution, fiducial limits, pobit and logit analysis.
- 3. *Regression*: Linear regression and correlation, curvilinear regression method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.
- 4. *Parametric tests* : Testing hypothesis, types of errors, tests of significance based on normal distribution, test of significance for correlation coefficients.
- 5. *Non-parametric tests* : Data characteristics and non-parametric procedures, chi-square test, sign test, Wilcoxon sign rank test, goodness of fit Mann-Whitney etc.
- 6. *Experimental design:* Randomization in completely randomized and latin square designs, factorial design, cross over and parallel design, bio-availability and bio-equivalence.
- 7. *Techniques:* Bioassay dose effect, relationships, LD<sub>50</sub>, ED<sub>50</sub>, probability calculations, Statistical quality control, shewhart control charts, statistical procedures in assay development.

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Code: MPT-101 Contact: 4L Credits: 3 Full marks: 100

1. Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

2. Infrared spectroscopy

Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

3. Ultraviolet spectroscopy :

Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore s ® s\*, h®s\*,p® p\*, h® p\*, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

4. Nuclear Magnetic Resonance spectroscopy :

A. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

B. 13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

5. Mass Spectrometry:

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

6. Thermal analysis:

Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

- 7. Pharmacological evaluation of drugs in biological fluids: Bioassay.
- 8. Microbiological assays.

### 9. Radioimmunoassays.

10. Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index, palisade ratio, vein-islet number, and vein-termination number.

Bio-pharmaceutics & Pharmacokinetics

### Code: MPT-116 Contact: 3L

# Credits: 2

# Full marks : 100

- 1. Introduction, concentration time profile, plotting the data, different fluid compartments and blood flow rates compartment models.
- 2. Protein and tissues binding, factors effecting protein binding kinetics of protein binding, determination of rate constants and different plots (direct, scatchard and reciprocal), significance volume of distribution, implications and in vitro methodologies.
- 3. *Pharmacokinetic characterization of drugs* : Absorption rate constants (Wagner-Nelson, Loo-Reigeiman methods) Limitations, lag-time, pharmacokinetics in presence of lag-time, Flip-flop model.
- 4. Drug disposition, renal clearance, mechanism of clearance, clearance ratio, determination of clearance, hepatic clearance, % drug metabolized, relationship between blood flow, intrinsic clearance, hepatic clearance and protein binding, different volumes of distribution, significance and integration kinetics.
- 5. Pharmacokinetics of multiple dosing, dosage regimen design based on mean average, minimum and maximum, plasma serum concentrations, limited fluctuation methods, Repeated one point method, Dosage adjustment in disease patients.
- 6. Nonlinear pharmacokinetics, direct, linear and orbit graph methods of dosing. Non-linear pharmacokinetics due to drug-protein binding.
- 7. Bio-availability and variations in blood leveis, disease states on bio-availability, bio-availability and biologic response, pharmacodynamic models.
- 8. In-vitro and in-vivo co-relations.
- 9. Animal models, Factors influencing the bio-availability of disposition of drugs and application of this information to optimize the therapy.
- 10. BA/BE, absorption in drug development

# **Books Recommended :**

- 1. Milo Gibaldi and Donald Perrier, "Pharmacokinetics", Drugs and Pharm. Sci. Series, Vol. 15, Marcel Dekker Inc., N.Y.
- 2. J.C.Wagner, "Fundamentals of Clinical Pharmacokinetics", Drug Intelligence Publications, Hamilton, 1975.
- 3. Bert N. LaDu, "Fundamentals of Drug Metabolism & Disposition", Waverley Press Inc., Baltimore, 1972.
- 4. T.Z.Lsaky, "Intestinal Absorption & Malabsorption", Raven Press, N.Y., 1975.
- 5. J.T.Carstensen, "Theory of Pharm.Systems", Vols. 1-3, Academic Press, N.Y.
- 6. H.S. Beans, A.H.Beckett and J.E.Caraless, "Advances in Pharm.Sci.", Vol.1 to 4

 J.T.Carstensen, "Drug Stability : Principles and Practices", Drugs and Pharm. Sci. Series, Vol. 43, Marcel Dekker Inc., N.Y.

**Pharmaceutical Technology Lab** : (4 hr. per week)

Code: MPT-196 Contact: 3L

# Credits: 2

### Full marks : 100

- 1. Experiment based on pre-formulation studies of dosage form.
- 2. Preparation and evaluation of sustained release dosage form, transdermal drug delivery system, microcapsules, micro-emulsions, solid dispersion of drug in polymer and ocular dosage form.
- 3. Dissolution studies of different dosage forms and in-vivo and in-vitro co-relation studies.

### Pharmaceutical Analysis Lab. (4 hr per week)

Code: MPT-191 Contact: 3L

### Credits: 2

### Full marks : 100

- 1. Practical based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.
- 2. Microbial analysis of Vitamins and Anti-biotics
- 3. Pharmacological Bioassay of some drugs.

# **SEMESTER-II**

### **Drug delivery System**

### Code: MPT-206(1) Contact: 3L

# Credits: 2

### Full marks : 100

- 1. Biopharmaceutic and pharmacokinetic aspects of PO CRDDS. Computation of desired release rate and dose for CR, release DDS. Pharmacokinetic design for DDS, Intermittent zero order and first order rlease.
- 2. Mathematical models for novel drug delivery systems: Membrane diffusion, diffusion controlled, biodegradable, osmotic pumps.
- 3. Peroral controlled-release delivery: Case studies.
- 4. Transdermal / Skin drug delivery systems: Principles of skin permeation, sorption promoters, pharmacokinetics of skin permeation, development and evaluation of transdermal devices.
- 5. Transdermal controlled: Release delivery, case studies (both iontophoresis and passive diffusion and combination approaches)
- 6. Parenteral drug delivery: Selection, design and development, polymer microspheres and dispersed DDS.
- 7. Strategies and design, in-vitro / in-vivo considerations, factor effecting controlled release drug delivery systems.
- 8. Protein/peptide drug delivery systems, enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.
- 9. Drug targeting: Microspheres, nanoparticles, brain specific delivery, liposomes, monoclonal antibodies.
- 10. Localized drug delivery systems case studies.
- 11. Drug delivery strategies: Case studies, drug delivery systems and drug development.
- 12. Flow sheet diagram for the manufacturing of infusion fluids as per recent GMP guidelines.

# **Books Recommended :**

1. Joseph R. Robinson, "Sustained and Controlled Release Drug Delivery Systems", Drugs & Pharm. Sci. Series, Vol. 6, Marcel Dekker Inc., N.Y.

2. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y.

3. J.N.Nixon, "Microencapsulation", Drugs and Pharm. Sci. Series, Vol. 3, Marcel Dekker Inc., N.Y.

4. G. Jolles and R.H.Wooldridge, "Drug Design - Faact or Fantasy?" Academic Press, 1984.

5. J.R.Robinson and Vincent H.L. Lee, "Controlled Drug Delivery", Drugs and Pharm. Sci. Series, Vol.29, Marcel Dekker Inc., N.Y.

6. R.L.Juliano, "Drug Delivery Systems", Oxford University Press, Oxford, 1980.

M.I.Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data
 E.B.Roche, "Design of Biopharmaceutical Properties through prodrug and analogs", Am. Pharm.

Assoc. Academy of Pharm. Sci., 1977.

9. Lisbeth, Illum & Stanley S. Davis : "Polymers in Controlled Drug Delivery", Wright, Bristol (1987). **Pharmaceutical Bio-technology** 

# Code: MPT-209

Contact : 4L

# Credits: 3

# Full marks : 100

- 1. Systems and methods of molecular biology: Introduction to genetic engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells, use of mutants, genetic analysis of mutants, genetic recombination, complementation.
- 2. Gene cloning: Nucleic acid isolation cloning vectors (some examples), enzymes used in molecular cloning, cloning methods (some examples)
- 3. Gene expression: Gene expression, some examples in E. coli in baculovirus in mammalian cells.
- 4. Fermentation technology: Design, operation and characteristics of fermentation processes, cell growth and production regulation, product biosynthesis and accumulation, instrumentation and bio-process control.
- 5. Industrial enzymes in drug development: Penicillin amidase, carbohydrase enzymes, chymosin from calf stomach, future directions.
- 6. Antibiotic biosynthesis genes and their use in developing new antibiotic from micro organisms. Methods for isolating new antibiotics, genetic systems and molecular tools for analysis of antibiotic, bio-synthesis, cloning and analysis of antibiotic biosynthesis genes, genetically engineered hybrid antibiotics.
- 7. Second generation molecules via site-specific gene alteration, second generation protein program design, examples of engineered proteins of therapeutic potential, methods of protein drug delivery future perspective.
- 8. Prospects in gene therapy, Potential approach to gene therapy, somatic cell gene transfer, prospects and limitations.
- 9. Biotechnology in pharmaceutical industry: Major areas for biotechnology in the pharmaceutical industry such as antibiotics, sexual re-combination, recombinant DNA technology, monoclonal antibody, regulatory proteins (human insulin, interferon, therapeutic peptides) commercial aspects, priorities for future biotechnological research.
- 10. Sterilization and sterility testing : principle, validation of different sterilization processes, methods, industrial sterilizer, air handling unit and sterility testing of different types of dosage form.

# **Books Recommended** :

- 1. J.D.Watson, "Molecular Biology of the cell".
- 2. J.D.Watson and Tooze, "Recombinant DNA techniques" : A short course.
- 3. Benjamin Levin, "Genes V".
- 4. Peppler, "Microbial Technology" I & II.
- 5. Old & Primrose, "Genetic Manipulations"
- 6. I.P. 1996, Vol.-I & II

# PROCESS VALIDATION AND CGMP

# Code: MPT-212 Contact: 4L

# Credits: 3

### Full marks : 100

- 1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Quality audits etc.
- 2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development.
- 3. Development of new analytical method and its validation.
- 4. In-process quality control tests for various dosage forms including packaging and labeling operations.
- 5. Brief introduction to general requirements of health regulatory agencies such as US FDA, WHO etc. Preparation of documents for new drug application and export registration.
- 6. History and various phases of drug development and drug approval, Investigational New drug (IND), New Drug Application (NDA) (Phase I-IV): content and format, Abbreviated new drug application (ANDA), Content, development flow sheet and format, exclusivity, concept of paragraph I to IV, Clinical study and basic concepts of Good clinical practice.
- 7. Concepts in validation, validation of manufacturing and analytical equipment. Process validation in production of pharmaceuticals. Electronic records (21CFR11)
- 8. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER

### **Books Recommended:**

- 1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
- 2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
- 3. S. Bolton, "Pharmaceutical Statistics : Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
- 4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.

### PHYSICAL PHARAMCEUTICS Code : MPT-206(2) Contact : 2L

### Credits: 1

Full marks : 50

1. SOLIDS

Particle characterization by size, shape and surface of individual particle and for contacted particle. Handling of solids, pharmaceutical granulation, compression and compaction properties of binary mixtures, lubricant sensitivity, characterization of granules and compacts, physics of tablet compression, Heckel plot, direct compression, advanced tablet coating techniques

# 2. DISSOLUTION:

Theory of dissolution, concept of drug release, Dissolution test apparatus: different designs, factors affecting dissolution rate. Dissolution of different dosage forms: solids, suspensions, topicals, suppositories and controlled release systems.

### 3. SURFACTANT SYSTEM

Phase behaviour of surfactant in binary and ternary systems. Factors affecting phase behaviour, Micellization; micelle structure, shape, size factors affecting CMC and miclle size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of solubilization, solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Hydrotrophy in pharmaceuticals, surfactants in emulsions and suspensions. Biological implications of surfactants; effect on: dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity.

4. Drug delivery gels, synthetic hydrogels-their preparation. Diffusion properties of swollen hydrogels, methods of modifying release kinetics.

**Bio-pharmaceutics Lab :** 

Code: MPT-296

Credits: 2

Full marks : 100

Contact hour : 60 hr per semester

Experiment based on bio-availability studies of different drug formulations.

### SEMESTER - III

### **Research Methodology and Clinical Trials**

Code: MPT-314

Credits: 2

Full marks :

### Contact hour : 3 hr per week

Information technology: subject classification and cataloguing, literature searches, data bases electronic and libraries, referencing and bibliographies, electronic communications.

- · Good clinical practice.
- · Good Laboratory Practice
- Ethics including consent and insurance
- · Adverse drug reaction surveillance
- · Randomization
- · Clinical trial design
- · Data management/statistics
- · Protocol preparation
- · Case record forms
- Evaluation of Reports and Report Writing
- · International guidelines for Clinical Research
- Use of unregistered medicines for Research

# **INSTRUCTIONS**

- 1. Each Semester will consist of a minimum of 15 weeks instructions :
- 2. Internal assessment of Theoreticals (30%) will be based on two class tests of 10 marks in each of the theory subject during each semester and 10 marks for class attendance of student in each subject.
- 3. Internal assessment of practicals (30%) will be based on day to day attendance, viva, laboratory record etc. There will be no separate class test in practicals. The question papers of university examinations shall be set by both the internal and external examiners. The choice in question papers shall be restricted to 25% only. Complete coverage of prescribed syllabus in university question papers is desired.
- 4. A minimum of 75% attendance in theory and practical classes is compulsory.
- 5. A student has to get minimum 45% mark in theory and 50% marks in practical separately to pass the subject.
- 6. Pass mark in aggregate will be 50% of the total marks.
- 7. A student will secure 1<sup>st</sup> class if he/she obtains 60% of total marks and 1<sup>st</sup> class with honours, if he/she obtains 75% of the total marks.
- 8. A student will be promoted to next higher semester with a maximum of two back papers (including practical).
- 9. A student will get a maximum of 4 yrs. time from the date of admission to complete the degree course.

# <u>PRECIES OF TOTAL GRADES IN M. PHARMACY PROGRAMME</u> (PHARMACEUTICS, PHARMACEUTICAL CHEMISTRY & PHARMACOLOGY)

SEMESTER	MINIMUM	MAXIMUM
SEM I		17
SEM II		13
SEM III		10
SEM IV		12
TOTAL CREDIT		52

**NOTE**: THE ENTIRE COURSE HAS BEEN DESIGNED ON THE BASIS OF AICTE & JADAVPUR UNIVERSITY, BIT, MESRA & PILANI COURSE STRUCTURE. THIS IS TO BE CONSIDERED AT THE TIME OF FINALISATION OF THE CURRICULUM.

# PROPOSED STRUCTURE FOR THEORY & PRACTICAL PAPERS WITH CONTACT HOURS PER WEEK AND CREDIT POINTS FOR MASTER DEGREE IN PHARMACEUTICAL TEHCOLOGY (M. PHARMA) IN PHARMACOLOGY

		A. <u>THE</u>	ORY					
SL. NO.	CODE	THEORY		CONTACTS (PERIODS/WEEK)			CREDITS	
				L	Т	Р	TOTAL	
01	MPT-108(1)	General Pharmacology		4			4	3
02	MBS-101	Bio-Statistics (Common paper)		4			4	2
03	MPT-101	Modern Pharmaceutical Analytical Techniques (Common paper)		4			4	3
04	MPT-108(2)	Advanced Pharmacology		3			3	2
		Sessio	onal					
05	MPT-181	Seminar						1
06	MPT-198	Pharmacology Lab				4	4	3
	MPT-191	Pharmaceutical Analysis Lab.				4	4	3
							23	17
FULL	MARKS FOR	PAPER WITH 2 / 3 CREDIT POINT	= 1	00			11	
FULL	MARKS FOR	PAPER WITH 1 CREDIT POINT	= 5	0				

=

200

# **SEMESTER-I**

FULL MARKS FOR PAPER WITH 9 CREDIT POINT = 300

FULL MARKS FOR PAPER WITH 5 CREDIT POINT

# SEMISTER-II

		A. <u>THEORY</u>					
SL. NO.	CODE	THEORY	CONTACTS CRED (PERIODS/WEEK)			CREDITS	
			L	Т	Р	TOTAL	
01	MPT-208(1)	Clinical Pharmacology	3			3	2
02	MPT-209	Pharmaceutical Bio-technology	4			4	3
03	MPT-212	Process validation & CGMP (Common paper)	4			4	3
04	MPT-208(2)	Molecular Pharmacology	3			3	2
		Sessional	•				
05	MPT-281	Seminar					1
06	MPT-293	Pharmacology Lab.			4	4	2
						18	13

# SEMISTER-III

A. <u>THEORY</u>							
SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)				CREDITS
			L	Т	Р	TOTAL	
01	MPT-314	Research Method & Clinical Trials	3			3	2
01	MPT-391	Synopsis					5
02	MPT-392	Presentation					3
						3	10

# SEMISTER-IV

SL. NO.	CODE	THEORY	CONTACTS (PERIODS/WEEK)			CREDITS	
			L	Т	Р	TOTAL	
01	MPT-493(1)	Thesis					9
02	MPT-493(2)	Defence of Thesis					3
							12
reser	ice of External	sentation of 1 <sup>st</sup> semester and Thesis and Defe Examiner(s). The Final Credit should be nternal and external examiners.					

### SYLLABUS FOR M. PHARM IN PHARMACOLOGY

### **SEMESTER-I**

### **GENERAL PHARMACOLOGY**

Code : MPT-108(1) Contact : 4L Credits: 3 Full marks : 100

### GENERAL PHARMACOLOGY (1<sup>st</sup> Sem)

1. a) Identify drug absorption, distribution, metabolism and elimination potential through the concept of ionization as defined by the Henderson-Hassel-batch equation.

b) Discuss the role of lipid solubility and route of administration relative to drug absorption, distribution, metabolism and elimination.

2. a) Drug discovery process: Principles, Techniques and Strategies used in

new drug discovery. Regulations for laboratory animal care and ethical requirements.

(b) Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical design employed in biological standardization. Bioassay of histamine, Insulin, Sexhormone, Oxytocin and acetylcholine.

- 3. Pre-clinical and clinical models employed in the screening of new drugs belonging to following categories: Analgesic antipyretics, anti-inflammatory, anti-anxiety agents, anti-depressant drugs, anti-convulsants, anti-diabetics, local anesthetics and anti-histaminic.
- 4. Alternative to animal screening procedure. Models of study drug metabolism.
- 5. Adverse drug reactions and drug interactions. Principle of toxicity evaluation and determination of  $LD_{50}$ ,  $ED_{50}$ , and  $TD_{50}$ .
- 6. Basic mechanism of membrane transport, membrane transporters in therapeutic drug responses, membrane transporters and adverse drug responses

**Bio-Statistics** 

Code : MBS-101 Contact : 4L Credits: 2

Full marks : 100

- 1. An introduction to statistics and bio-statistics collection and organisation of data: Graphical and pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, coefficient of variation, mean error, relative error, precision and accuracy.
- 2. *Probability:* Definition and probability distributions, normal, binominal and polynominal distributions, continuous data distribution, fiducial limits, pobit and logit analysis.
- 3. *Regression*: Linear regression and correlation, curvilinear regression method of least squares, curve fitting, multiple regression and correlation, significance of correlation and regression.
- 4. **Parametric tests :** Testing hypothesis, types of errors, tests of significance based on normal distribution, test of significance for correlation coefficients.

- 5. *Non-parametric tests* : Data characteristics and non-parametric procedures, chi-square test, sign test, Wilcoxon sign rank test, goodness of fit Mann-Whitney etc.
- 6. *Experimental design:* Randomization in completely randomized and latin square designs, factorial design, cross over and parallel design, bio-availability and bio-equivalence.
- 7. *Techniques:* Bioassay dose effect, relationships, LD<sub>50</sub>, ED<sub>50</sub>, probability calculations, Statistical quality control, shewhart control charts, statistical procedures in assay development.

# MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Code: MPT-101 Contact: 4L Credits: 3 Full marks: 100

1. Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

2. Infrared spectroscopy

Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

3. Ultraviolet spectroscopy :

Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore s ® s\*, h®s\*,p® p\*, h® p\*, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

4. Nuclear Magnetic Resonance spectroscopy :

A. 1H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

B. 13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

5. Mass Spectrometry:

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

6. Thermal analysis:

Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

- 7. Pharmacological evaluation of drugs in biological fluids: Bioassay.
- 8. Microbiological assays.
- 9. Radioimmunoassays.
- 10. Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index,

palisade ratio, vein-islet number, and vein-termination number.

# ADVANCED PHARMACOLOGY

Code :	<b>MPT-108(2)</b>
Contact:	3L
Credits :	2
Full Marks : 100	)

1. Gene therapy: Central concept of gene therapy, gene therapy for hereditary diseases, gene therapy for cancer, gene therapy for HIV. Antisense therapy, basic concept, mechanism of antisense therapy, examples of antisense therapy for the treatment of different diseases.

2. The role of Nitric oxide in various physiological functions and its importance in pharmacotherapy of disorders like hypertension, Angina and Erectile dysfunction.

3. Role of Cytokines as a biological response modifiers (a) Interleukins, (b) Colony Stimulation Factors (c) Tumor Necrosis Factors Alpha (TNF- $\infty$ ). Identify the target for immunosuppressive actions of the following drug agents such as Cyclosporine, Tacrolimus, Cortisteroids, Azathioprine, Methotrexate, Cyclophosphamide, Mycophenolate, CD3 antibodies including their mechanisms of action in imunosuppression.

4. Role of Prostaglandins, Bradykinins, Adhesion Molecules and NF  $\kappa$ B in various immunological and inflammatory disorders.

5. Emerging concepts and newer therapeutic interventions with special reference to atherosclerosis and obesity.

6. Neuropharmacology: Molecular and cellular mechanisms, Glutamate receptors, GABA and its receptors, catecholamine receptors, Serotonin receptors, the opioid receptors, strokes, neurodegeneration, antiepileptic drugs.

7. Physiological and Pathological Angiogenesis, Stimulator and Inhibitors of Angiogenesis, Modern antiangiogenic concept for the treatment of chronic diseases, Solid tumor and Cancer.

# PHARMACOLOGY LAB –I

Code:MPT-198Contact:4p/weekCredits: 3Full Marks : 100

- 1. Effect of Anti-depolarizing agents like pancuronium on acetylcholine-induced contraction of frog rectus abdominis muscle.
- 2. Identification of unknown sample of drug using frog rectus muscle.
- 3. Effect of papaverine on barium chloride-induced contraction of guinea pig ileum.
- 4. Identification of unknown sample of drug using guinea pig ileum.
- 5. Effect of Physostignine on regular pendular movement of rabbit intestine.
- 6. Identification of unknown sample of drug using of rabbit intestine.
- 7. Histopathological study of liver isolated from mice.
- 8. Histopathological study of pancreas isolated from mice.
- 9. Histopathological study of kidney isolated from mice.
- 10. Histopathological study of small intestine isolated from mice.

### Pharmaceutical Analysis Lab. (4 hr per week)

Code: MPT-191 Contact: 4p/week

Credits: 3

### Full marks : 100

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1. Practical based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.

Microbial analysis of Vitamins and Anti-biotics Pharmacological Bioassay of some drugs.

### SEMESTER-II

### CLINICAL PHARMACOLOGY

Code: MPT-208(1`) Contact: 3L

Credits: 3

### Full marks : 100

1. Definition and scope of clinical pharmacology, Evaluation of drugs in man, Official regulation of medicines, Classification and naming of drugs.

2. Drug therapy monitoring in special situations such as pediatric geriatric, pregnancy etc.

3. Racial gender and ethnic differences in drugs response.

4. Patient counseling and interviewing techniques, Improving patient compliance and patient monitoring.

5. Application to therapeutic drug monitoring (TDM), Pharmacist interventions in case of renal impairment, hepatic impairment and anti-coagulant therapy.

6. ADR monitoring, management and reporting of drug interactions and adverse drug reactions.

7. Discuss and identify appropriate chemotherapeutic agents for the major tissue sites of cancer.

### Pharmaceutical Bio-technology

Code: MPT-209 Contact: 4L

### Credits: 3

### Full marks : 100

- 1. Systems and methods of molecular biology: Introduction to genetic engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells, use of mutants, genetic analysis of mutants, genetic recombination, complementation.
- 2. Gene cloning: Nucleic acid isolation cloning vectors (some examples), enzymes used in molecular cloning, cloning methods (some examples)
- 3. Gene expression: Gene expression, some examples in E. coli in baculovirus in mammalian cells.
- 4. Fermentation technology: Design, operation and characteristics of fermentation processes, cell growth and production regulation, product biosynthesis and accumulation, instrumentation and bio-process control.
- 5. Industrial enzymes in drug development: Penicillin amidase, carbohydrase enzymes, chymosin from calf stomach, future directions.
- 6. Antibiotic biosynthesis genes and their use in developing new antibiotic from micro organisms. Methods for isolating new antibiotics, genetic systems and molecular tools for analysis of antibiotic, bio-synthesis, cloning and analysis of antibiotic biosynthesis genes, genetically engineered hybrid antibiotics.

- 7. Second generation molecules via site-specific gene alteration, second generation protein program design, examples of engineered proteins of therapeutic potential, methods of protein drug delivery future perspective.
- 8. Prospects in gene therapy, Potential approach to gene therapy, somatic cell gene transfer, prospects and limitations.
- 9. Biotechnology in pharmaceutical industry: Major areas for biotechnology in the pharmaceutical industry such as antibiotics, sexual re-combination, recombinant DNA technology, monoclonal antibody, regulatory proteins (human insulin, interferon, therapeutic peptides) commercial aspects, priorities for future biotechnological research.
- 10. Sterilization and sterility testing : principle, validation of different sterilization processes, methods, industrial sterilizer, air handling unit and sterility testing of different types of dosage form.

# **Books Recommended :**

- 1. J.D.Watson, "Molecular Biology of the cell".
- 2. J.D.Watson and Tooze, "Recombinant DNA techniques" : A short course.
- 3. Benjamin Levin, "Genes V".
- 4. Peppler, "Microbial Technology" I & II.
- 5. Old & Primrose, "Genetic Manipulations"
- 6. I.P. 1996, Vol.-I & II

# PROCESS VALIDATION AND CGMP

### Code: MPT-212 Contact: 4L

### Credits: 3

### Full marks : 100

- 1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Quality audits etc.
- 2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development.
- 3. Development of new analytical method and its validation.
- 4. In-process quality control tests for various dosage forms including packaging and labeling operations.
- 5. Brief introduction to general requirements of health regulatory agencies such as US FDA, WHO etc. Preparation of documents for new drug application and export registration.
- 6. History and various phases of drug development and drug approval, Investigational New drug (IND), New Drug Application (NDA) (Phase I-IV): content and format, Abbreviated new drug application (ANDA), Content, development flow sheet and format, exclusivity, concept of paragraph I to IV, Clinical study and basic concepts of Good clinical practice.
- 7. Concepts in validation, validation of manufacturing and analytical equipment. Process validation in production of pharmaceuticals. Electronic records (21CFR11)
- 8. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER

### **Books Recommended:**

- 1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
- 2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.

- 3. S. Bolton, "Pharmaceutical Statistics : Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
- 4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.

### MOLECULAR PHARMACOLOGY Code: MPT-208(2) Contact: 3L

### Credits: 2

### Full marks : 100

1. Introduction of Molecular Pharmacology. Techniques for the study of Molecular Pharmacology such as Western Blotting, Immunostaining, RT-PCR, Cloning, RIA, Cell Cultures etc.

2. Recombinant DNA technology and it's application in the production of Insulin.

3. Drug receptor interactions and second messenger systems. Signal transduction and termination of receptor activity. G - proteins and receptor structures, cAMP pathway, Phospholopase C, IP<sub>3</sub>, DAQ pathway.

4. Molecular Oncobiology: Causes of cancer, genetic of cancer, oncogenes, tumor suppressor genes.

5. Contrast the use of therapeutic agents for cancer chemotherapy versus immunosuppression in terms of dosage and degree of elective toxicity.

6. Molecular Neurobiology:

Molecular genetics of Alzheimer's disease, Myasthenia gravis and parkinsonism. Molecular mechanism and regulation of behavior.

### PHARMACOLOGY LAB –II Code : MPT-293 Contact : 4p/week

# Credits: 2

# Full marks : 100

- 1. Effect of CNS stimulants on mice.
- 2. Effect of CNS depressants in mice.
- 3. Evaluation of local anesthetic activity of lignocaine hydrochloride on rabbit cornea
- 4. Evaluation of anti-inflammatory effect of ibuprofen in carrageenin-induced acute inflammation model in rat's paw.
- 5. Evaluation of anti-inflammatory effect of unknown drug sample in carrageenin-induced acute inflammation model in rat's paw.
- 6. Determination of SGOT and SGPT value of blood sample of rabbits.
- 7. To study the effect of paracetamol treatment on the value of SGOT and SGPT of blood sample of rabbits.
- 8. Determination of cholesterol and triglyceride level in blood sample of rabbits
- 9. Determination of blood sugar and hemoglobin level in blood sample of rabbits.
- 10. Determination of ED50, LD50 and TD50 value.

### **SEMESTER - III**

### Research Methodology and Clinical Trials Code: MPT-314

Credits: 2

### Full marks :

### Contact hour : 3 hr per week

Information technology: subject classification and cataloguing, literature searches, data bases electronic and libraries, referencing and bibliographies, electronic communications.

- · Good clinical practice.
- · Good Laboratory Practice
- Ethics including consent and insurance
- · Adverse drug reaction surveillance
- · Randomization
- · Clinical trial design
- · Data management/statistics
- · Protocol preparation
- · Case record forms
- Evaluation of Reports and Report Writing
- · International guidelines for Clinical Research
- Use of unregistered medicines for Research