SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY

Department of Biotechnology			LP: BT18002 Rev. No: 00 Date: 02/01/2024
B.E/**B.Tech**/M.E/M.Tech	**: Biotechnology (VI Semeter)**	**Regulation: 2018A**	
PG Specialisation	**: -**		
Sub. Code / Sub. Name	**: BT18002/Biopharmaceutical Technology**		
Unit	**: I Introduction**	**(7 Hrs)**	

Unit Syllabus: Pharmaceutical industry, Drug discovery, design and development, Types of therapeutic agents and their uses, Economics and regulatory aspects.

Objective**: To impart knowledge on development of drugs and their regulatory aspects.**

Session No *	Topics to be covered	Ref	Teaching Aids
1.	Introduction to pharmaceutical Industry	T3- Ch. 1; Pg.1-3 T1- Sec I,Ch-1;Pg.1-26	LCD/Black Board
2.	Drug discovery	T2-Part C, Ch. 14; Pg. 242-268	LCD/Black Board
3.	Drug design	T2-Part C, Ch. 14; Pg. 242-268	LCD/Black Board
4.	Drug development: Preclinical trials, Drug metabolism studies, Pharmacology and stability tests, Clinical trials,	R1- Sec I, Ch.5; Pg. 67-75, R2- Ch.16; Pg. 559-570	LCD/Black Board
5.	Drug development: Chemical and process development	R2- Ch.16; Pg. 570- 573	LCD/Black Board
6.	Types of therapeutic agents and uses of therapeutic agents	T3- Ch. 1; Pg.1-3 T1- Sec I,Ch-1;Pg.1-26	LCD/Black Board
7.	Introduction to economics and regulatory aspects, Key stages in drug approval process and regulatory affairs	T3-Ch. 2; Pg. 9-16	LCD/Black Board

Content beyond syllabus covered (if any):
Nil

* Session duration: 50 minutes

Sub. Code / Sub. Name: BT18002/Biopharmaceutical Technology

Unit : II Drug Action, Metabolism And Pharmacokinetics (9 Hrs)

Unit Syllabus: Mechanism of drug action; physico-chemical principles of drug metabolism; radioactivity; pharmacokinetics.

Objective: To learn about the mechanism of drug action and pharmacokinetic behavior of the drug.

Session No *	Topics to be covered	Ref	Teaching Aids
8.	Introduction : Various routes of drug administration	R3-Unit 1, Ch.1; Pg. 1-4 T2- Ch.1; Pg.1- 4	Animated Video/LCD/Black Board
9.	Mechanism of drug action- Pharmacokinetics: Absorption of drug	R3-Unit 1, Ch.1; Pg. 4-8 T2- Ch.2; Pg.5- 75	Animated Video/LCD/Black Board
10.	Mechanism of drug action- Pharmacokinetics: Distribution of drug	R3-Unit 1, Ch.1;Pg. 8- 13 R1- Sec- I,Ch.3; Pg.37 T2- Ch.3; Pg.76-90 R3- Ch.4; Pg.91-110	Animated Video/LCD/Black Board
11.	Mechanism of drug action- Pharmacokinetics: Metabolism of drug	R3-Unit 1, Ch.1;Pg. 13- 16 R1- Sec- I,Ch.4; Pg.53-66 R2-Ch.12;Pg.439-475 T2- Ch.5; Pg.111-177	Animated Video/LCD/Black Board
12.	Physico-chemical principles of drug metabolism	R3-Unit 1, Ch.1;Pg. 13- 16 R1- Sec- I,Ch.4; Pg.53-66 R2-Ch.12;Pg.439-475 T2- Ch.5; Pg.111-177	LCD/Black Board
13.	Mechanism of drug action- Pharmacokinetics: Elimination of drug	R3-Unit 1, Ch.1;Pg. 16- 18 T2- Ch.1; Pg.178- 203	LCD/Black Board
14.	Pharmacokinetics – Biological half- life, Bioavailability, Bioequivalence, Clearance, Elimination rate constant, Plasma drug concentration –Time profile, Zero order, First order and Mixed order kinetics	R1- Sec- I,Ch.3; Pg.38-49 R2-Ch. 11; Pg. 403-436 R3– Unit I,Ch.1; Pg. 1- 24 T2- Ch.1; Pg.212- 229, Ch.12; Pg.282- 305	LCD/Black Board
15.	Pharmacokinetic Models: Compartment models, Non compartment models and Physiologic models. One-Compartment open model: Intravenous bolus administration, Intravenous infusion- Extra vascular administration, Urinary Excretion data. Two compartment open model: Intravenous bolus administration- Extra vascular administration. Nonlinear Pharmacokinetics: Causes of nonlinearity	R3-Unit I, Ch.1;Pg. 19- 24 T2- Ch.1; Pg.230-272	LCD/Black Board
16.	Radiopharmaceuticals	T1- Sec- VIII, Ch.18; Pg.559-589 R5- Sec- 1; Pg.59-95	LCD/Black Board
Content beyond syllabus covered (if any): Nil			

* Session duration: 50 mins

Sub. Code / Sub. Name: BT18002/Biopharmaceutical Technology

Unit : III Manufacture of Drugs, Process and Applications (7 Hrs)

Unit Syllabus: Types of reaction process and special requirements for bulk drug manufacture.

Objective: To introduce the basis of reaction process and requirements for bulk drug manufacture.

Session No *	Topics to be covered	Ref	Teaching Aids
17.	Types of reaction process: Chemical synthesis	T3-Ch. 5; Pg.75-77	LCD/Black Board
18.	Types of reaction process: Biotechnology based process (Fermentation) (r-DNA Technology), recovery and purification of a drug – techniques used (Filtration, Centrifugation,Etc.,), recovery and purification of a drug – advanced techniques (Chromatography, ultra filtration, etc.,)	T3-Ch. 5; Pg.77- 84	LCD/Black Board
19.	Key unit operations (Liquid material/ solid material handling, liquid/liquid separation technique, crystallization, solids isolation, drying, product finishing, Solvent recovery, packaging)	T3-Ch. 5; Pg.85-96	LCD/Black Board
20.	Production methods and consideration (Production, automation and control issues)	T3-Ch. 5; Pg.96- 100	LCD/Black Board
21.	Various Pharmaceutical ingredients/ excipients and its uses (Definition and types, handbook of pharmaceutical excipients and food and chemical codex)	T1-Sec II, Ch. 4; Pg. 127-132	LCD/Black Board
22.	Various Pharmaceutical ingredients/ excipients and its uses (Harmonization of standards, Appearance and Palatability)	T1-Sec II, Ch. 4; Pg. 132-139	LCD/Black Board
23.	Principles for layout of bulk production facilities	T3-Ch. 5; Pg.100-110 T3-Ch. 6; Pg.111-192	LCD/Black Board
Content beyond syllabus covered (if any): Nil			

* Session duration: 50 mins

Sub. Code / Sub. Name: BT18002/Biopharmaceutical Technology

Unit : IV Principles of Drug Manufacture **(15 Hrs)**

Unit Syllabus: Compressed tablets; dry and wet granulation; slugging or direct compression; tablet presses; coating of tablets; capsule preparation; oral liquid – vegetable drugs – topical applications; preservation of drugs; analytical methods and other tests used in drug manufacture; packaging techniques; quality management; GMP

Objective: To study in detail about principles for manufacturing various drug dosage forms.

Session No *	Topics to be covered	Ref	Teaching Aids
24.	Introduction – Different dosage forms	T1-Sec III, Ch. 6; Pg. 184, T1-Sec IV, Ch. 10; Pg. 272, T1-Sec VI, Ch. 13; Pg. 331	LCD/Black Board
25.	Tablet Formulation: Wet granulation	T3-Ch. 6; Pg.111-113 T1-Sec III, Ch. 8; Pg. 238- 240 R5- Sec- 4; Pg.235-266	Video Lecture
26.	Dry granulation	T3-Ch. 6; Pg.114- 118 T1-Sec III, Ch. 8; Pg. 240- 242	Video Lecture
27.	Compressed tablets	T3-Ch. 6; Pg.119 123 T1-Sec III, Ch. 8; Pg. 231-238	Video Lecture
28.	Direct compression, Tablet presses	T3-Ch. 6; Pg.119- 123 T1-Sec III, Ch. 6; Pg. 242- 243	LCD/Black Board
29.	Coating of tablets: Film coating	T3-Ch. 6; Pg.123-125 T1-Sec III, Ch. 8; Pg. 246- 248	LCD/Black Board
30.	Sugar coating	T3-Ch. 6; Pg.124 T1-Sec III, Ch. 8; Pg. 244- 246	LCD/Black Board
31.	Capsule preparation	T3-Ch. 6; Pg.126- 131 T1-Sec III, Ch. 7; Pg. 203 - 225	LCD/Black Board
32.	Preparation of oral liquids	T3-Ch. 6; Pg.132- 133 T1-Sec VI, Ch. 13; Pg. 331- 376 R5- Sec- 4; Pg.313-343	LCD/Black Board
33.	Preparation of topical applications	T3-Ch. 6; Pg.133- 137 T1-Sec IV, Ch. 10; Pg. 272- 294 R5- Sec- 4; Pg.267-312	LCD/Black Board
34.	Vegetable drugs, Preservation of drugs	T1-Sec II, Ch. 4; Pg. 139- 141	LCD/Black Board
35.	Analytical methods used in drug manufacture and Other tests used in drug	T1-Sec III, Ch. 8; Pg. 231-236	LCD/Black Board
36.	Packaging techniques	T3-Ch. 6; Pg.177- 200	LCD/Black Board
37.	Quality management: Good manufacturing practices for API- Introduction	T3-Ch. 3; Pg.17- 22	LCD/Black Board
38.	Good manufacturing practices for API- GMP design requirements and GMP reviews of design	T3-Ch. 3; Pg.22- 37	LCD/Black Board
Content beyond syllabus covered (if any): Nil			

* Session duration: 50 mins

Sub. Code / Sub. Name: BT18002/Biopharmaceutical Technology

Unit : V Biopharmaceuticals **(7 Hrs)**

Unit Syllabus: Various categories of therapeutics like vitamins, laxatives, analgesics, contraceptives, antibiotics, hormones and biological

Objective: To impart knowledge about the pharmacodynamics of various categories of therapeutics.

Session No *	Topics to be covered	Ref	Teaching Aids
39.	Sources of various vitamins. Mechanism of action of various vitamins	R3 – Unit IV, Ch.20; Pg. 240 - 247	LCD/Black Board
40.	Pharmacodynamics of various laxatives	R3 – Unit VI, Ch. 28; Pg. 338-339	LCD/Black Board
41.	Pharmacodynamics of various contraceptives	R3 – Unit V Ch. 25; Pg. 305-307 R3 – Unit VIII, Ch. 41; Pg.499- 518	LCD/Black Board
42.	Pharmacodynamics of action of various analgesics	R3 – Unit III,Ch.14; Pg. 159-170	LCD/Black Board
43.	Pharmacodynamics of various hormones	R3 – Unit V, Ch. 23, 24, 25 & 26; Pg. 275-318 R1- Sec- VII,Ch.37;Pg. 643 773	LCD/Black Board
44.	Pharmacodynamics of various antibiotics	R3 – Unit VII, Ch. 30, 31 & 32; Pg. 347- 386 R1- Sec- VIII,Ch.43;Pg. 773- 898	LCD/Black Board
45.	Pharmacodynamics of various biologicals	R3 – Unit VII, Ch. 40; Pg. 489-498 T1 -Sec VII, Ch. 16; Pg. 509-538 R4 –Ch. 3; Pg. 45-91	LCD/Black Board

Content beyond syllabus covered (if any):
Pharmacodynamics of Antiviral and Anticancer drugs.

* Session duration: 50 mins

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Text Books:

T1. Loyd V. Allen Jr., Nicholas G. Popvich and Howard C. Ansel, "Ansels pharmaceuticaldosage forms and drug delivery systems", 9th Edition, Wolters Kluwer publishers, New Delhi, 2011.

T2. Brahmankar D.M., "Biopharmaceutics and Pharmacokinetics A Treatise", Vallabh Prakashan, India, 1995.

T3. Bennett Bill, Cole Graham, "Pharmaceutical production: An Engineering Guide", IChemE, UK, 2003.

References:

R1. Gareth Thomas, "Medicinal Chemistry - An introduction". 2nd Edition, John Wiley, England, 2007.

R2. Katzung B.G., "Basic and Clinical Pharmacology", 11th Edition, Tata MaGraw- Hill, India, 2009.

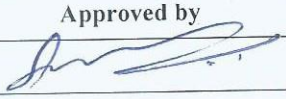
R3. Finkel Richard, Clark Michelle A., Cubeddu Luigi X., "Lippincott's Illustrated Reviews Pharmacology" 4th Edition, Wolters Kluwer / Lippincott Williams & Wilkins, 2009.

R4. Bernd Meibohm, "Pharmacokinetics and Pharmacodynamics of biotech drugs", Wiley-VCH, 2006.

R5. Shayne Cox Gad, "Pharmaceutical Manufacturing Handbook", John Wiley & Sons, Inc., 2008.

Video Lecture Link:

https://www.youtube.com/playlist?list=PLODKZZeKAWb-PMMqRrD4hNUG4v7bkVbt1

	Prepared by	Approved by
Signature		
Name	Dr. S. Pandi Prabha	Dr. E. Nakkeeran
Designation	Professor, Biotechnology	Professor and HOD, Biotechnology
Date	02/01/2024	02/01/2024
Remarks *: ---		
Remarks *: ---		

PK Pandi

* If the same lesson plan is followed in the subsequent semester/year it should be mentioned and signed by the Faculty and the HOD