SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY

Department of Biotechnology	LP: BT22041 Rev. No: 01 Date: 10/01/2025
B.E/**B.Tech**/M.E/M.Tech **: Biotechnology** **Regulation: 2022** **PG Specialisation : -** **Sub. Code / Sub. Name : BT22041/Biopharmaceuticals and Biosimilars** **Unit : I Introduction (9 Hrs)**	

Unit Syllabus: Pharmaceutical industry, Drug sources, Discovery and Development phases, Types of therapeutic agents and their uses, Economics and regulatory aspects, Role of patents in the drug industry.

Objective: To give strong foundation and advanced information on biopharmaceutical aspects in relation to drug development.

Session No *	Topics to be covered	Ref	Teaching Aids
1.	Introduction to biopharmaceuticals	R3- Ch.1; Pg. 1	BB/LCD
2.	Introduction to Pharmaceutical Industry	T1- Sec I, Ch-1; Pg.1-26 R3- Ch.1; Pg. 1-11	BB/LCD
3.	Drug Sources	R3- Ch.5; Pg. 105-119	BB/LCD
4.	Drug Discovery	T2-Part C, Ch. 14; Pg. 242-268	BB/LCD & Blended Learning - Video Lecture
5.	Drug Design	T2-Part C, Ch. 14; Pg. 242-268	BB/LCD & Blended Learning - Video Lecture
6.	Drug development: Preclinical Trials, Drug metabolism studies, Pharmacology and stability tests, Clinical trials	R3- Sec I, Ch.5; Pg. 67-75	BB/LCD & Blended Learning - Video Lecture
7.	Types of therapeutic agents and uses of Therapeutic agents	T1- Sec I,Ch-1;Pg.1-26	BB/LCD
8.	Introduction to economics and regulatory aspects, Key stages in drug approval process and regulatory affairs	T1- Sec I,Ch-1;Pg.11-25 T1- Sec I,Ch-1;Pg.44-48	BB/LCD
9.	Role of patents in the drug industry	R3- Ch.1; Pg. 67-69	BB/LCD
Content beyond syllabus covered (if any): Nil			

* Session duration: 50 minutes

Sub. Code / Sub. Name: BT22041/ Biopharmaceuticals and Biosimilars

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 gain knowledge in physicochemical properties, pharmacology and pharmacokinetics.

Session No *	Topics to be covered	Ref	Teaching Aids
10.	Introduction : Various routes of drug administration	T2- Ch.1; Pg.1- 4	BB/LCD
11.	Absorption of drug	T2- Ch.2; Pg.5- 75	BB/LCD & Blended Learning - Video Lecture
12.	Distribution of drug	R3 - Sec- I,Ch.3; Pg.37 T2- Ch.3; Pg.76-90	BB/LCD & Blended Learning - Video Lecture
13.	Metabolism of drug	R3- Sec- I,Ch.4; Pg.53-66 T2- Ch.5; Pg.111-177	BB/LCD & Blended Learning - Video Lecture
14.	Elimination of drug	T2- Ch.1; Pg.178- 203	BB/LCD
15.	Pharmacokinetics – Biological half- life, Bioavailability, Bioequivalence, Clearance, Elimination rate constant	R3 - Sec- I,Ch.3; Pg.38-44 T2 – Ch.12; Pg.282- 305	BB/LCD
16.	Pharmacokinetics: Plasma drug concentration –Time profile, Zero order, First order and Mixed order kinetics	R3- Sec- I,Ch.3; Pg.45-49 T2- Ch.1; Pg.212- 229	BB/LCD
17.	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	T2- Ch.1; Pg.230-272	BB/LCD
18.	Radiopharmaceuticals	T1- Sec- VIII, Ch.18; Pg.559-589	BB/LCD
Content beyond syllabus covered (if any): Nil			

* Session duration: 50 mins

Sub. Code / Sub. Name: BT22041/ Biopharmaceuticals and Biosimilars

Unit : III Biopharmaceuticals **(9 Hrs)**

Unit Syllabus: Biopharmaceutical classification system, Various categories of therapeutics like Vitamins, Laxatives, Analgesics, Contraceptives, Antibiotics, Hormones and Biologicals.

Objective: To acquire the students with knowledge on different types of biopharmaceuticals.

Session No *	Topics to be covered	Ref	Teaching Aids
19.	Biopharmaceutical classification system	T1- Sec I, Ch-1; Pg.42-43 AR 1	BB/LCD
20.	Sources of various vitamins. Mechanism of action of various vitamins	R4 – Unit IV, Ch.20; Pg. 240 – 247 AR 2	BB/LCD
21.	Mechanism of action of various laxatives	R4 – Unit VI, Ch. 28; Pg. 338-339 AR 3	BB/LCD & Blended Learning - Video Lecture
22.	Mechanism of action of various analgesics	R4 – Unit III,Ch.14; Pg. 159-170 AR 4	BB/LCD & Blended Learning -
23.	Mechanism of action of various contraceptives	R4 – Unit V Ch. 25; Pg. 305-307 R4 – Unit VIII, Ch. 41; Pg.499-518 AR 5	BB/LCD & Blended Learning - Video Lecture
24.	Mechanism of action of various antibiotics	R3- Sec- VIII,Ch.43;Pg. 773- 898	BB/LCD
25.	Mechanism of action of various hormones	R3- Sec- VII,Ch.37;Pg. 643 773	BB/LCD
26.	Mechanism of action of various biological – Recombinant proteins	T1 -Sec VII, Ch. 16; Pg. 509-538 R1 -Ch. 10,11; Pg. 280-282, 291-305	BB/LCD
27.	Mechanism of action of various biological – Recombinant vaccines, monoclonal antibodies, etc.,	T1 -Sec VII, Ch. 16; Pg. 509-538 R1 -Ch. 12; Pg. 371-379	BB/LCD
Content beyond syllabus covered (if any): Pharmacodynamics of Antiviral and Anticancer drugs (AR 6)			

* Session duration: 50 mins

Sub. Code / Sub. Name: BT22041/ Biopharmaceuticals and Biosimilars

Unit : IV Biosimilars – Approval Pathway **(9 Hrs)**

Unit Syllabus: Definition - Biogenerics and Biosimilars, Biosimilar medicine – Importance, INN nomenclature system, Key trends in biosimilar product development, Production of biosimilar products, Difficulties with biosimilar drugs, Biosimilars - Non clinical and clinical study, Regulation and approval process, Future prospects.

Objective: To introduce the students about the importance of biogenerics and biosimilars and its development pathway.

Session No *	Topics to be covered	Ref	Teaching Aids
28.	Definition - Biogenerics and Biosimilars	R2 - Ch. 1; Pg. 8-15	BB/LCD
29.	Biosimilar medicine – Importance	T1 -Sec VIII, Ch. 19; Pg. 591-641	BB/LCD
30.	INN nomenclature system	R1 -Ch. 10; Pg. 272 AR 7	BB/LCD
31.	Key trends in biosimilar product development	T3 – Ch. 4; Pg. 45-99	BB/LCD
32.	Production of biosimilar products	T3 - Ch. 6; Pg. 149-187 T4 – Part III, Ch. 8; Pg. 173-185	BB/LCD & Blended Learning - Video Lecture
33.	Difficulties with biosimilar drugs	R2 - Ch. 6; Pg. 375-394	BB/LCD
34.	Biosimilars - Non clinical and clinical study	T4 – Part II, Ch. 6; Pg. 123-143	BB/LCD
35.	Biosimilars - Regulation and approval process	T4 – Part II, Ch. 5; Pg. 107-121	BB/LCD
36.	Biosimilars - Future prospects	T4 – Part I, Ch. 1; Pg. 19-21	BB/LCD
Content beyond syllabus covered (if any): Nil			

* Session duration: 50 mins

Sub. Code / Sub. Name: BT22041/ Biopharmaceuticals and Biosimilars

Unit : V Characterization of Biosimilars (9 Hrs)

Unit Syllabus: Requirements for the characterization of biosimilars – Analytic characterization to test for similarity in primary amino acid structure, higher-order structure (Chromatography, Protein sequencing, Circular dichroism, UV-Vis, Mass and Nuclear magnetic resonance spectroscopies), Detection of post translational modifications, assessment of optimal target binding, and testing for impurities and optimal potency.

Objective: To familiarize the students about the analytical techniques used for characterization biosimilars.

Session No *	Topics to be covered	Ref	Teaching Aids
37.	Requirements for the characterization of biosimilars	T4 – Part IV, Ch. 12; Pg. 305-319 AR 8	BB/LCD
38.	Analytic characterization to test for similarity in primary amino acid structure, higher-order structure - Reversed-phase chromatography (RPC), Hydrophobic interaction chromatography	T3 - Ch. 8; Pg. 232-233 AR 9	Blended Learning - Video Lecture
39.	Analytic characterization to test for similarity in primary amino acid structure, higher-order structure - Ion-exchange chromatography, Size-exclusion chromatography	T3 - Ch. 8; Pg. 217-231 AR 9	BB/LCD & Blended Learning - Video Lecture
40.	Analytic characterization to test for similarity in primary amino acid structure, higher-order structure - Protein sequencing	T3 - Ch. 10; Pg. 279-281 AR 9	BB/LCD
41.	Analytic characterization to test for similarity in primary amino acid structure, higher-order structure - Circular dichroism spectroscopy	AR 9	BB/LCD
42.	Analytic characterization to test for similarity in primary amino acid structure, higher-order structure - UV-Vis spectroscopy	T3 - Ch. 10; Pg. 288 AR 10	BB/LCD
43.	Analytic characterization to test for similarity in primary amino acid structure, higher-order structure – Mass and Nuclear magnetic resonance spectroscopy	R1 -Ch. 7; Pg. 184 AR 9	BB/LCD
44.	Detection of post translational modifications	AR 8	BB/LCD
45.	Assessment of optimal target binding, and testing for impurities and optimal potency	T3 - Ch. 10; Pg. 271-272 AR 8	BB/LCD
Content beyond syllabus covered (if any): Nil			

* Session duration: 50 mins

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Text Books:

1. Loyd V. Allen Jr, Nicholas G. Popvich and Howard C. Ansel, "Ansels pharmaceutical dosage forms and drug delivery systems", 12th Edition, Wolters Kluwer, 2021.
2. Brahmankar D.M, "Biopharmaceutics and Pharmacokinetics - A Treatise", 3rd Edition, Vallabh Prakashan, 2017.
3. Niazi Sarfaraz K, "Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues", CRC Press, 2006.
4. Gutka H. J, Yang H, & Kakar S (Eds.), "Biosimilars: regulatory, clinical, and biopharmaceutical development" Part of the book series: AAPS Advances in the Pharmaceutical Sciences Series (AAPS, volume 34), Springer. 2018.

References:

1. Walsh G, "Pharmaceutical Biotechnology-Concepts and Application", 1st Edition, John Wiley and Sons, 2007.
2. Chow S. C, "Biosimilars: Design and Analysis of Follow-on Biologics", 3rd Edition, CRC Press, 2013.
3. Thomas G, "Medicinal Chemistry - An introduction". 2nd Edition, John Wiley and Sons, 2007.

Additional References:

1. Samineni, R., Chimakurthy, J. and Konidala, S., 2022. Emerging role of biopharmaceutical classification and biopharmaceutical drug disposition system in dosage form development: A systematic review. Turkish journal of pharmaceutical sciences, 19(6), p.706. https://doi.org/10.4274/tjps.galenos.2021.73554
2. https://go.drugbank.com/drugs
3. Bashir A, Sizar O. Laxatives. [Updated 2024 Jan 30]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537246/
4. Queremel Milani DA, Davis DD. Pain Management Medications. [Updated 2023 Jul 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560692/
5. Cooper DB, Patel P. Oral Contraceptive Pills. [Updated 2024 Feb 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430882/
6. https://www.esmo.org/oncology-news/pharmacokinetic-and-pharmacodynamic-interactions-between-anticancer-and-antiviral-drugs
7. Serafini M, Cargnin S, Massarotti A, Tron GC, Pirali T, Genazzani AA. What's in a name? Drug nomenclature and medicinal chemistry trends using INN publications. Journal of Medicinal Chemistry. 2021 Apr 13: 64(8):4410-29. https://doi.org/10.1021/acs.jmedchem.1c00181
8. Peter M. Sullivan, Lisa M. DiGrazia, Analytic characterization of biosimilars, American Journal of Health-System Pharmacy, 2017, Apr 15: 74(8): 568–579, https://doi.org/10.2146/ajhp150971
9. https://www.americanpharmaceuticalreview.com/Featured-Articles/345863-Biosimilars-and-Their-Structural-Characterization/
10. Richard L Easton, 2022. Structural characterization methods for biosimilars: fit-for-purpose, qualified or validated. Generics and Biosimilars Initiative Journal (GaBI Journal). 11(1), p. 41. https://doi.org/10.5639/gabij.2022.1101.007

Blended Learning - Video Lecture Link:

1. Blended Learning Video Lecture Link

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COURSE DELIVERY PLAN - THEORY

	Prepared by	Approved by
Signature		
Name	Dr. S. Pandi Prabha	Dr. E. Nakkeeran
Designation	Professor and AHOD, Biotechnology	Professor and HOD, Biotechnology
Date	10/01/2025	10/01/2025
Remarks *: The same lesson plan is followed in the subsequent semester/year.		
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* If the same lesson plan is followed in the subsequent semester/year it should be mentioned and signed by the Faculty and the HOD