SRI VENKATESWARA COLLEGE OF ENGINEERING

COURSE DELIVERY PLAN - THEORY

Department of Biotechnology			LP: BY 22005 Rev. No: 01 Date: 15/12/2022
B.E/B.Tech/M.E/**M.Tech**	**: Biotechnology**	**Regulation: 2022**	
PG Specialisation	**: Biotechnology**		
Sub. Code / Sub. Name	**: BY 22005/Advanced Biopharmaceutical Technology**		
Unit	**: I Introduction**	**(8 Hrs)**	

Unit Syllabus: Drugs discovery and Development phases; Drugs and Cosmetics ACT and regulatory aspects; Definition: Generics and its advantages; Biogenerics and Biosimilars; The role of patents in the drug industry; Protein-based biopharmaceuticals; Introduction to pharmacokinetics and pharmacodynamic principles (factors affecting the ADME process); bioavailability, bioequivalence.

Objective: To impart knowledge on pharmaceutical industry, development of drugs and their regulatory aspects.

Session No *	Topics to be covered	Ref	Teaching Aids
1.	History of pharmaceutical industry	TB1 - Pg 27-45, RB1 – Pg 2-3	LCD
2.	Drugs discovery and Development phases	TB1 - Pg 46-66, TB3 - Pg. 559-573, RB5 - Pg. 67-75	LCD
3.	Drugs and Cosmetics ACT and regulatory aspects	TB1 - Pg 11-18, RB6 - Pg.9-6	LCD
4.	Definition: Generics and its advantages; Biogenerics and Biosimilars	TB2 - Pg 265-271, Internet resources-1,2	LCD
5.	The role of patents in the drug industry	RB1 – 67 - 70, RB4 - 57 - 65, RB7 - Pg 274-278	Online class - GCR
6.	Protein-based biopharmaceuticals	TB2 - Pg 84, Internet resources-2	LCD
7.	Introduction to pharmacokinetics and pharmacodynamic principles	TB1 - Pg 105-138, RB1 – 74 - 77, RB8 - Pg. 1-8	Smart class
8.	Bioavailability and Bioequivalence	TB1 - Pg 265-272, 416-425, TB3 - Pg.439-475, RB8 - Pg. 1- 24	Smart class

Content beyond syllabus covered (if any):
Computers in medicinal chemistry, Quantitative structure activity relationships (QSAR).
Case study: Discovery and development of Antiangiogenesis drugs and Oxaminoquine

* Session duration: 50 minutes

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Sub. Code / Sub. Name: BY 22005/Advanced Biopharmaceutical Technology

Unit : II Dosage forms **(10 Hrs)**

Unit Syllabus: Definition of Dosage forms, Classification of dosage forms (solid unit dosages – Tablets, capsules; liquids – solutions, lotions, suspension etc; semi-solid – ointments, creams, gel, suppositories, etc; Parenterals, Aerosols etc).

Objective: To study in detail about principles for manufacturing various drug dosage forms, mechanism of drug action and pharmacokinetic behavior of the drug.

Session No *	Topics to be covered	Ref	Teaching Aids
9.	Definition of Dosage forms, Classification of dosage forms	TB1 - Pg 90-141	Smart class
10.	Solid unit dosages – Tablets	TB1 - Pg 225 - 252, RB6 - Pg.111-125	LCD
11.	Solid unit dosages – Capsules	TB1 - Pg 203 - 220, RB6 - Pg.126- 131	LCD
12.	Liquids – solutions, lotions, suspension etc	TB1 - Pg 331, RB6 - Pg.132- 133	LCD
13.	Semi-solid – ointments, creams,	TB1 - Pg 272 - 278, RB6 - Pg.133- 137	LCD
14.	Semi-solid - Gel, Suppositories, etc	TB1 - Pg 278 - 290, Pg 312 - 320	LCD
15.	Parenterals,	TB1 - Pg 431 - 488, Internet sources-3	Online class - GCR
16.	Aerosols	TB1 - Pg 414 - 426, Internet sources-4	Smart class

Content beyond syllabus covered (if any):
Applications of Pharmacokinetic Principles, The use of pharmacokinetics in drug design, Relationship between pharmacokinetics and pharmacodynamics.

* Session duration: 50 mins

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Sub. Code / Sub. Name: BY 22005/Advanced Biopharmaceutical Technology
Unit : III Advanced Drug Delivery Systems **(9 Hrs)**

Unit Syllabus: Controlled release dosage forms – Rationale – Principle and factor influencing – Design and Fabrication – Microencapsulation – Liposomes – Niosomes – Transdermal drug delivery – Ocular, Vaginal and Uterine controlled release.

Objective: To study in detail about drug delivery systems and biologicals.

Session No *	Topics to be covered	Ref	Teaching Aids
17.	Drug delivery systems	Internet sources-5,6	LCD
18.	Controlled release dosage forms	TB1- Pg 289-313	LCD
19.	Principle and factor influencing drug delivery	TB1- Pg 260-274	LCD
20.	Design and Fabrication of drug	TB1 - Pg. 663-665	Online class - GCR
21.	Microencapsulation Liposomes, Niosomes	TB1 - Pg 257-262, 426-452	LCD
22.	Transdermal drug delivery	TB1 - Pg 294-310	LCD
23.	Ocular controlled release	TB2 - Pg 106-107, 422, Internet resources-7	Smart class
24.	Vaginal controlled release	TB1 - Pg 165-170, 655, Internet resources-8	Smart class
25.	Uterine controlled release	TB1 - Pg 654-668, Internet resources-9	Smart class
Content beyond syllabus covered (if any): Nanobased drug delivery systems.			

* Session duration: 50 mins

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Sub. Code / Sub. Name: BY 22005/Advanced Biopharmaceutical Technology

Unit : IV Biosimilars **(10 Hrs)**

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

Objective: To impart knowledge on biosimilar drug development

Session No *	Topics to be covered	Ref	Teaching Aids
26.	Biosimilar medicine & its importance	TB2 - Pg 521-535	Smart class
27.	INN nomenclature system	Internet sources 10	Smart class
28.	Biosimilar product development	TB2 - Pg 265-270	LCD
29.	Production of biosimilar products	Internet sources 11	LCD
30.	Difficulties with biosimilar drugs	Internet sources 12	LCD
31.	Non clinical and clinical study	Internet sources 13,14	LCD
32.	Regulation and approval process	Internet sources 14	Online class - GCR
33.	Future prospects	Internet sources 15	Online class - GCR
Content beyond syllabus covered (if any): Pharmacodynamics of Antiviral and Anticancer drugs.			

* Session duration: 50 mins

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Sub. Code / Sub. Name: BY 22005/Advanced Biopharmaceutical Technology

Unit : V Nanotechnology in Pharmacology **(8 Hrs)**

Unit Syllabus: Nanotechnology in point-of-care diagnostics, Nanopharmacology & drug targeting, Cellular uptake mechanisms of nanomaterials, In vitro methods to study antibacterial and anticancer properties of nanomaterials.

Objective: To learn the importance of nanopharmacology and its applications.

Session No *	Topics to be covered	Ref	Teaching Aids
34.	Introduction to Nanopharmacology	RB9 - Pg 37-84, NPTEL Notes	Online class - GCR
35.	Nanotechnology in point-of-care diagnostics	Internet resources 16, NPTEL Notes	Online class - GCR
36.	Nanopharmacology & drug targeting	RB9 - Pg 85-111, NPTEL Notes	LCD
37.	Nanomaterials – Overall view	RB9- Pg 3-36, NPTEL Notes	LCD
38.	Cellular uptake mechanisms of nanomaterials	Internet resources 17, NPTEL Notes	LCD
39.	In vitro methods to study antibacterial properties of nanomaterials	RB9 - Pg 393-400, NPTEL Notes	Smart class
40.	In vitro methods to study anticancer properties of nanomaterials	RB9 - Pg 281-312, NPTEL Notes	Smart class

Content beyond syllabus covered (if any):
Therapeutic effect of various protein based pharmaceuticals.

* Session duration: 50 mins

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TEXT BOOKS

1. Loyd V.Allen, Jr. Nicholas G.Popvich,Howard C. Ansel, Ansels pharmaceutical dosage forms and drug delivery systems,9th edition,2011,Wolters Kluwer publishers,New Delhi.
2. Crommelin Dwan J.A., Robert D. Sindelar and Bernd Meibohm, "Pharmaceutical Biotechnology: Fundamentals and application", Springer, 4th Edition, 2013.
3. Katzung B.G. Basic and Clinical Pharmacology, 11th Edition, 2009. Tata MaGraw- Hill,India

REFERENCE BOOKS

1. Gary Walsh, Pharmaceutical Biotechnology concepts and applications, 2011, Wiley India Pvt Ltd. New Delhi.
2. Karen Whalen, Carinda Field and Rajan Radhakrishnan "Lippincott's Illustrated Reviews Pharmacology" 7th Edition, 2019. Wolters Kluwer / Lippincott Williams & Wilkins.
3. Brahmankar D. M., Sunil B. Jaiswal. Biopharmaceutics and Pharmacokinetics A Treatise. 2005, Vallabh Prakashan, India.
4. Gary Walsh, Pharmaceutical Biotechnology concepts and applications, 2003, Wiley India Pvt Ltd. New Delhi.
5. Gareth Thomas. Medicinal Chemistry - An introduction. 2nd Edition,2007,John Wiley.England.
6. Bennett. Bill; Cole, Graham. Pharmaceutical production: An Engineering Guide, 2003,IChemE.UK
7. Graham L. Patrick. An Introducrion to Medicinal Chemistry. 5th Edition,2013.Oxford University Press.
8. Finkel, Richard, etal., "Lippincott's Illustrated Reviews Pharmacology" 4th Edition.,2009. Wolters Kluwer / Lippincott Williams & Wilkins.
9. Keservani, R.K. and Sharma, A.K. eds., 2019. Nanoparticulate drug delivery systems. CRC Press.

INTERNET RESOURCES

1. http://www.biopharma.com/rader_CBI_biogenerics_talk.pdf
2. http://www.biopharma.com/biosimilars/definitions.html
3. http://apps.who.int/phint/en/p/docf/
4. http://www.aerosols.wustl.edu/education/AerosolBasics/Sources.htm
5. http://pubs.acs.org/subscribe/archive/mdd/v04/i04/html/MDD04FeatureVogelson.html
6. http://www.azonano.com/article.aspx?ArticleID=1538
7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4289909/
8. https://www.primescholars.com/articles/intra-vaginal-drug-delivery-systeman-overview.pdf
9. https://www.sciencedirect.com/science/article/abs/pii/S0169409X09001446
10. http://www.biopharma.com/biosimilars/definitions.html
11. https://gabionline.net/biosimilars/general/Amgen-explains-the-steps-of-manufacturing-a- biosimilar
12. https://www.drugpatentwatch.com/blog/top-5-challenges-faced-biosimilars/
13. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6192287/
14. https://www.fda.gov/drugs/biosimilars/review-and-approval
15. https://www.marketsandmarkets.com/Market-Reports/biosimilars 40.html?gclid=CjwKCAiAheacBhB8EiwAItVO226n-Ux_sDBsgMYpCtJLaIFcVxpmSyRqdp0bwParkbRFxwrldO09vRoClG4QAvD_BwE
16. https://www.sciencedirect.com/science/article/pii/S0956566316308417
17. https://www.sciencedirect.com/science/article/abs/pii/S0169409X1930050X

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	Prepared by	Approved by
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Name	N. Kanagam	Dr. E. Nakkeeran
Designation	Assistant Professor	Professor
Date	15.12.2022	15.12.2022
Remarks *: -		
Remarks *: -		

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