

2.12 COURSE OUTLINE

2.12.1 BCM 3347 - INTRODUCTION TO PHARMACEUTICAL BIOTECHNOLOGY (BIOCHEMISTRY VII)

Pre-requisites: BCM 1331; BCM 1341; BCM 2346

Credit Units: 3

2.12.2 Purpose of the course;

To provide the student with a working knowledge of the preparation, stability, formulation and regulation of biotechnology pharmaceutical products.

2.12.3 Expected Learning Outcomes of the Course;

At the end of the course, the student should be able to:

- List and explain the origins, modes of activities, stability and formulation of biological drugs;
- Interpret the outcome of experiments that involve the use of recombinant DNA technology and other common gene analysis techniques;
- State the quality control procedures of biotechnology products;
- Evaluate different techniques for separation and purification of cell types;
- Conduct techniques for measuring cell turnover, growth and cytotoxicity.

2.12.4 Course Content;

Introduction: Overview of new technology, **DNA technology:** Recombinant DNA technology, The hybridoma technology, Basic site-directed mutagenesis, Products of biotechnology, Diagnostic products, Criteria for regulatory approval of biotechnology. **Genetic Engineering:** DNA as the primary genetic material, Central Dogma of Molecular Biology, Structure of DNA, RNA and Protein, Transcription and translation, genetic code, DNA Cloning and Recombinant DNA molecules. **Tissue Culture:** Definition, Types and sources of tissue culture, Culture collection and resource centers, Gene Bank. **Fermentation Technology:** Categories of biotechnology medicine, Intermediate products: Vitamins, amino acids. **Scale-up process** (manufacturing of commercial biotechnology product). Biotechnological products and their indications. Antibodies in research, diagnostics and therapeutics; Delivery of Biotechnology products; Stability of Biotechnology products; **Legal and Ethical Perspectives:** Genetic test and its importance, Pre-natal genetic test. **Assessment of genetic technology:** Ethical, Religious, Social, Economic, Cultural and Ideological.

2.12.5 Mode of Delivery;

Lectures, power point presentations, and class discussions: The instructor will give lectures in class to explain to the students various topics in Molecular Biology. The lectures will take a participatory approach where the instructor will involve students by frequently asking them questions that are meant to keep them alert in class and trigger class discussions. The instructor will also be free to answer questions from the students in the course of the lectures. **Laboratory learning and Experiments:** The lecturer, together with the laboratory technical staff, will take the students through practical sessions, beginning with **demonstrations**. The students will thereafter be expected to use pre formulated laboratory manuals to carry out various practical exercises. They will be expected to write out their findings in their laboratory workbooks for marking. **Video demonstrations and/or CD-Roms** in Pharmaceutical Biotechnology will be shown in class when available after the relevant topic has been

covered. **Assignment criteria:** Students will be given several individual or group research assignments on relevant topics.

2.12.6 Instructional Materials and/or Equipment;

Lecture notes or power points for presentation; Tutorials; Video demonstrations; CD-Roms; Dissection kits; Microscopes; Text books; Practical Manuals, biochemical reagents; glassware; biochemical analytical equipment; biochemical charts

2.12.7 Course Assessment;

2.12.7.1 Distribution of Marks

Attendance & Participation	5%
Continuous Assessment Tests /Quizzes	5%
Term Paper	10%
Oral examination	10%
Mid-Quarter Exam	15%
Final Exam	25%
Laboratory exercises	30%
Total	<u>100%</u>

2.12.7.2 Grading

90 – 100	A
87 - 89	A ⁻
84 - 86	B ⁺
80 - 83	B
77 - 79	B ⁻
74 - 76	C ⁺
70 - 73	C
67 - 69	C ⁻
64 - 66	D ⁺
62 - 63	D
60 - 61	D ⁻
00 - 59	F

2.12.8 Core Reading Materials for the Course;

Crommelin Daan, J. A., Sindelar, R. D., Meibohm, B. (Eds) (2007). *Pharmaceutical Biotechnology: Fundamentals and Applications*. 3rd Edition. CRC Press

Groves, M. J. (2006). *Pharmaceutical Biotechnology: Fundamentals and Essentials*. 2nd Edition. CRC Press INC

Ninfa, A. J., Ballou, D. P., Benore, M. (2009). *Fundamental Laboratory Approaches for Biochemistry and Biotechnology*. 2nd Edition. Wiley, Hoboken, NJ, USA

2.12.9 Recommended Reference Materials;

Cammack, R., Attwood, T., Campbell, P., Parish, H., Smith, A., Vella, F., and Stirling, J. (Eds). (2006). *Oxford Dictionary of Biochemistry and Molecular Biology*. 3rd Edition. Oxford University Press, London

Meisenberg, G., Simmons, W. H. (2012). *Principles of Medical Biochemistry*. 3rd Edition. Saunders, Elsevier, Philadelphia

Nelson, D. L. & Cox, M. M. (2012). *Lehninger Principles of Biochemistry*. 6th Edition. W. H. Freeman & Co., New York