2.12 COURSE OUTLINE

2.12.1 PHM 5418: PHARMACEUTICAL MICROBIOLOGY (PHARMACEUTICS VIII)

Pre-requisites: MIC 2361; PHM 3411

Credit Units: 4.5

2.12.2 Purpose of the course;

This course introduces the students to the concepts of sterile products and formulations. The content includes introduction to sterile products; facilities, garb and equipment; aseptic calculations; properties of sterile products; aseptic techniques; sterile product preparations such as total parenteral nutrition (TPN).

2.12.3 Expected Learning Outcomes of the Course;

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

- Define and explain microbial contamination, and the need for proper aseptic techniques
- List different types of sterile formulations and biological products
- Describe how to formulate, handle, admix and reconstitute sterile products
- Define and describe solubility, stability, and shelf life of sterile products
- Describe the concept and application of immunoassay methods
- Measure and explain tonicity, osmolarity and osmolality
- Outline the methods of pyrogen and sterility testing
- Outline the methods of evaluating disinfectant/antiseptic activity

2.12.4 Course Content;

Review of the Biology of microorganisms. **Pharmaceutical and Industrial Microbiology:** media selection and preparation, techniques and experimental design, minimum inhibitory concentrations and quantitative applications. **Preservation of pharmaceutical preparations:** Preservation of aqueous, non-parenteral preparations. Preservation of topical preparations with a consideration of the factors affecting preservative efficiency. Industrial production of antibiotics, microbial production of vitamins, foods, basic chemicals, steroids. Antibiotic assay methods, pyrogen and methods of measurement of resistance, genetic basis of resistance, microbial, contamination and methods of detection. **Biological Products:** Immunological preparations: Immunostimulants, Immunossupressants, Immunological diseases. **Enzymes and Hormones. Immunoassay:** Concepts and applications; Fluorescent immunoassay, enzyme immunoassay, enzyme multiplied immuno assay, enzyme linked immune-sorbent assay, autoradiography, isotope dilution analysis and activation analysis. **Antimicrobial Agents:** Disinfectants and Antiseptics; Methods of pharmaceutical **sterilization**; Methods of the determination of **sterilization efficiency**; RW and CM tests, BB test, MSST test. **Pyrogen & Sterility Testing**. **Practicals:** Preparation of sterile products, Pyrogen & Sterility tests.

2.12.5 Mode of Delivery;

Lectures, power point presentations, and class discussions. These will take a participatory approach. **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 then write out their findings in their laboratory workbooks. **Video demonstrations and/or CD-Roms** on Sterile & Aseptic production when available, after the relevant topic has been covered. **Assignment criteria:** Students will be given several individual or group research assignments on topics relevant to the course. These could include lectures, discovery learning, problem-based learning, experimental learning, group-based learning, independent studies and e-learning.

2.12.6 Instructional Materials and/or Equipment;

Lecture notes or power points for presentation; Tutorials; Video demonstrations; CD-Roms; Microscopes; Equipment and reagents for practical microbiology; Practical Manuals; Culture media; Text books; microbiology charts and atlases.

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	**100%**

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;

Denyer, S. P., Hodges, N., Gorman, S. P., Brendan F. Gilmore, B. F. Eds. (2011). Hugo and Russell's Pharmaceutical Microbiology. 8th Edition. Wiley-Blackwell, USA

Kar, A. (2008). Pharmaceutical Microbiology. New Age International, New Delhi

2.12.9 Recommended Reference Materials;

Delves, P. J., Martin, S. J., Dennis R. Burton, D. R., Roitt, I. (2011). Roitt's Essential Immunology. Wiley, New York

Hanlon, G. & Hodges, N. (2013). Essential Microbiology for Pharmacy and Pharmaceutical Science. Wiley-Blackwell

Hodges, N., & Hanlon, G. (2011). Industrial Pharmaceutical Microbiology: Standards & Controls. Euromed Communications

Loyd, Jr., V. A., Adejare, A., Desselle, S. P., Felton, L. A. (Eds). (2012). Remington: The Science and Practice of Pharmacy (2 Volumes). 22nd Edition. Pharmaceutical Press, LONDON