

UNIVERSITY OF JAFFNA
BACHELOR OF PHARMACY
SECOND YEAR FIRST SEMESTER EXAMINATION – JULY 2013
PHAMB 2106 PHARMACEUTICAL MICROBIOLOGY

Date: 27.08 .2013

Time: 02 Hours

Answer all six questions.

1. Describe the
 - 1.1. sources and routes of microbial contamination in Pharmaceutical Products. (50 Marks)
 - 1.2. role of microorganisms in spoilage of pharmaceutical products. (50 Marks)
2.
 - 2.1. List the factors influencing the growth of micro organism. (30 Marks)
 - 2.2. Describe different physical methods to control the growth of micro organisms. (70 Marks)
3.
 - 3.1. Classify clean area in pharmaceutical manufacturing. (15 Marks)
 - 3.2. Write the procedures that could be carried out in each area mentioned in 3.1. (25 Marks)
 - 3.3. What is aseptic processing? (20 Marks)
 - 3.4. How do you carry out environmental monitoring under aseptic processing? (40 Marks)
4.
 - 4.1. Define 'sterility testing'. (20 Marks)
 - 4.2. Describe Membrane filtration used for sterility testing. (50 Marks)
 - 4.3. Mention the limitations of Sterility Test. (30 Marks)
5.
 - 5.1. Define microbial assay of antibiotics (20 Marks)
 - 5.2. Describe briefly the application of microbial assay of antibiotics. (30 Marks)
 - 5.3. Describe briefly the method of microbial assay of Penicillin. (50 Marks)
6.
 - 6.1. Describe diagrammatically the relationship between Quality Assurance, Good Manufacturing Practice and Quality control. (10 Marks)
 - 6.2. Tabulate the differences between Quality Assurance and Quality control. (30 Marks)
 - 6.3. List the objectives of good laboratory Practice (GLP) (20 Marks)
 - 6.4. Briefly explain the standard operating procedure (SOP) in microbiological laboratories (40 Marks)