



International Islamic University Chittagong

Department of Pharmacy

Program: B. Pharm (Hons)

Examination: Final

Session: Autumn-2021

Course Code: Pharm-4703

Course Title: **Pharmaceutical Quality Assurance**

Full Marks: 50

Time: 2 Hours and 30 Minutes

Group A (Marks: 20)

Answer any two questions

1. a) Point out the in-process control checks of the following process: sterilization, coating and mixing. 2
- b) What requirements should be fulfilled before starting dispensing of raw materials? 4
- c) Summarize the functions of a quality control department. 4

2. a) Mention the applications of settle plate and surface swab techniques. 2
- b) Sometimes trace amount of contaminant causes serious hypersensitivity reaction. Explain with examples and how can you prevent such kind of contamination? 4
- c) How can you monitor the particulate, chemical and microbial contaminations during production? 4

3. a) During tablet manufacturing how will you control bulk and intermediate product. 5
- b) Illustrate the golden rules of cGMP 5

Group B (Marks: 30)

Answer any three questions

4. a) Define product recall. Who can perform product recall? 2
- b) Illustrate the importance of different methods adopted for internal quality audit. 4
- c) Systematically describe the process of market complain investigation. 4

5. a) How can you identify good management and poor management company? 2
- b) Sketch out the key operations of a pharmaceutical industry. What factors can influence the management on quality? 4
- c) Summarize the process of auditing to suppliers. 4

6. a) Is it possible to produce quality products using limited facilities? Explain. 2
- b) How does Abraham Maslow's correlate human needs for quality motivation? 4
- c) Compare between cost of compliance and cost of non-compliance with examples. 4

7. Write short notes on- 2.5×4
- a) DGDA c) SOP
- b) Batch Deviation d) MHRA