

UKA TARSADIA UNIVERSITY

M.Pharm. (PT) (1st Semester)

Subject :040120102 - Pharmaceutical Technology-I

Duration: 3 Hours

Max. Marks: 70.

Instructions:

1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks allocated to that question.
5. Draw diagrams/figures whenever necessary.

Section-1

Q-1 (A) Answer the following.

[07]

- I) Motivating participants is important in technology transfer. Comment.
- II) What do you understand by batch and continuous process.?
- III) What do you understand by Unit operations?
- IV) Enumerate different steps of tablet compression.
- V) Give the specification of moist heat sterilization?
- VI) Name two polymers used for film coating.
- VII) Which dryer should be used for thermolabile material?

Q-1 (B) Answer the following in brief. (Any 4)

[08]

- I) Enumerate theories of filtration.
- II) What do you understand by convective mixing?
- III) What is levigation?
- IV) Explain briefly Elutriation.
- V) Give basic considerations to be addressed during an effective technology transfer.
- VI) Prepare a reduced written document cum checklist for any development and technology transfer program.

Q-2 Answer the following.

[10]

- A) Describe the significance and rationale for technology transfer of pharmaceuticals.

OR

- A) Write a note on pretransfer consideration in technology transfer of pharmaceuticals.

- B) Describe Filtration with special reference to formulation and production of pharmaceuticals.

OR

- B) Write a note on any two batch dryers used in production of pharmaceuticals.

Q-3 Answer the following in detail. (Any 2)

[10]

- A) Continuous processing of pharmaceuticals should be preferred for manufacturing of pharmaceuticals. Comment.
- B) Discuss briefly WHO guidelines on technology transfer of pharmaceuticals.
- C) Discuss technology transfer team with their responsibilities.

Section-2

Q-4 (A) Do as directed.

[07]

- I) Define: Overages
- II) What do you understand by control strategy?
- III) Which test is to be performed on boxes used for pharmaceutical packaging?
- IV) Which parameters affect selection of packaging system?
- V) How alkalinity is removed in type I glass?
- VI) Collapsible metal tube is preferred for packaging. Comment

VII) Name materials used for blister packaging.

Q-4 (B) Answer the following in brief. (Any 4)

[08]

- I) Give primary principles of quality risk management?
- II) What is Risk identification as per ICH Q9?
- III) Prepare a model flow chart for overview of a typical quality risk management process.
- IV) Enlist different categories of packaging system.
- V) Enlist different types of rubber for preparing closures.
- VI) Explain briefly paperboard as packaging material.

Q-5 Answer the following.

[10]

- A) Describe the general attributes of pharmaceutical products being covered by these guidelines.

OR

- A) Write a note on "Pharmaceutical Development Studies".
B) What are the desirable properties of pharmaceutical package?

OR

- B) Describe Glass as pharmaceutical packaging material.

Q-6 Answer the following in detail. (Any 2)

[10]

- A) Write a note on tamper evident packaging system.
B) Describe various tests to be performed on plastic container
C) Discuss the scope and objectives of ICH Q10 Guidelines.