



DBZ-MQA-204-T Seat No. _____

M. Pharm (Quality Assurance) (Sem. II)
Examination

July - 2022

**MQA-204T - Pharmaceutical Manufacturing
Technology**

Time : 3 Hours

[Total Marks : 75]

Instructions : (1) Figure to the right indicates full marks.
(2) Draw neat and clean diagram as required.

1 Answer the following questions : $10 \times 2 = 20$

- (a) What is the meaning of CIP and SIP ? What are the differences between them?
- (b) Enlist different pharmaceutical package stability tests.
- (c) What are the limitations of traditional approach of manufacturing?
- (d) Draw a flow diagram for getting license of formulation industry for India
- (e) Classify packaging material with suitable examples.
- (f) Discuss in brief : Transportation test.
- (g) Enlist the factor influencing industrial plant layout.
- (h) Enlist the different problems encountered during coating of tablet and capsule production.
- (i) What is the importance of wall and floor treatment in advance sterile product manufacturing?
- (j) Draw neat and clean diagram of layout for sterile and aseptic area of pharmaceutical industry.

2 Answer any two out of the following : $2 \times 10 = 20$

- (a) Write a detail note on process automation in pharmaceutical industry for improved tablet production.
- (b) Define the term QbD. What are the advantages of it? Write a detail note on various elements and tools of QbD with suitable examples.

(c) Discuss IPQC test of the following formulation :

(a) Ointment (c) Emulsion

(b) Suspension (d) dry powder

3 Answer any **seven** out of the following : $7 \times 5 = 35$

(a) Write a brief note on automation in SVP and LVP.

(b) Write a detail note on Lyophilization technology.

(c) Discuss the importance of PAT as a driver for improving quality and reducing costs in pharmaceutical products.

(d) Write a brief note on general principles of production planning.

(e) Discuss IPQC tests for tablet formulation.

(f) Enlist the various types of tamper resistant packaging. Discuss any three in detail.

(g) Write a brief note on coating technology.

(h) Explain briefly about factors influencing plant location.

(i) Explain briefly AQBd and QbD for Drug products.