



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 : 10×2=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 : 2×10=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 : **7×5=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.
-