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PAV-MQA-204-T Seat No. _____

M. Pharm. (Sem. II) Examination

August / September - 2020

MQA-204-T : Pharmaceutical Manufacturing Technology

Time : **3** Hours] [Total Marks : **75**

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

1 Answer the following question : **10×2=20**

(a) What is the importance of plant location in development of pharma industry?
(b) What is the significance of CMA (QbD) in pharmaceutical product development?
(c) What is FFS technology of pharmaceutical manufacturing?
(d) Which type of material./drug/formulation processed through lyophilization technique?
(e) What is the principle of sterilization in place (SIP)?
(f) Enlist the IPQC tests for capsule dosage form.
(g) Draw a manufacturing flow chart of aseptic-ointment manufacturing.
(h) Enlist the main components of production planning.
(i) What is the application of spheronizer in pharmaceutical manufacturing?
(j) What is the difference between bubble pack and blister pack?

2 Answer any **two** out of the following questions : **2×10=20**

(a) Why plant layout is important? Discuss plant layout for sterile and aseptic area. Enumerates factor affecting selection of such areas.
(b) Give detailed account for manufacturing flow chart and IPQC testing for tablet dosage form.
(c) What is QbD? What are the advantages, disadvantages of QbD? Discuss each element of QbD with suitable example.

3 Answer any **seven** out the following questions : **7×5=35**

(a) Discuss in detail : PAT as a tool for improving pharmaceutical quality and reducing cost.

(b) How QbD applied for any analytical method? Discuss with suitable example.

(c) What do you mean by container-closure integrity? Discuss quality control test of packaging material.

(d) Give the significance of tablet coating. Discuss the process of coating with its current advancement.

(e) Give manufacturing flow chart for large and small volume parenterals.

(f) Write a short note: Aseptic process technology for Suspension and Emulsion.

(g) What care and precaution should be performed in sterile area, with reference to environmental control, floor treatment, personnel flow, and utility location?

(h) Write an informative note: Automation in pharmaceutical manufacturing.

(i) Discuss in detail: Glass and Plastic-as a material of choice in pharmaceutical packaging.
