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PF-MQA204T

Seat No. _____

M. Pharm. (Sem. II) (CBCS) Examination

July - 2018

MQA-204T : Pharmaceutical Manufacturing Technology

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

1 Answer all the following questions : **20**

(1) Discuss in brief: Factor influencing plant layout.

(2) Give difference between small volume parenterals and large volume parenterals.

(3) Discuss general principle behind production planning.

(4) Enlist IPQC test for ointment and dry powder.

(5) What is coating? Enlist different steps involved during coating process.

(6) Discuss non pharmacopoeial tests for plastic containers.

(7) Classify different glass containers.

(8) Discuss in brief: Drug plastic interaction.

(9) What is PAT? Why it required?

(10) Define and discuss: QTPP, CQA

2 Answer the following questions : (Any **Two**) **20**

(1) What is QbD? Why it required? Discuss different elements of QbD.

(2) Discuss different in process quality control tests for any one sterile dosage form.

(3) Discuss how stability of packaging material is evaluated.

3 Answer the following questions : (Any **Seven**) **35**

(1) Discuss legal requirements for API and formulation industry.

(2) Discuss process automation with specific reference to sterile semi solid dosage form.

(3) Write principle and equipment for lyophilisation.

(4) Discuss IPQC test for tablet.

(5) Write a note on fluidized bed coating.

(6) Write about different types of closures and closure liner.

(7) Discuss relationship between QA, QC and GAMP.

(8) Which are different types of tablet packaging? Differentiate blister and strep packing.

(9) Discuss quality control of packaging material and filling equipment.
