J-MQA-104-T Seat No. _____

M. Pharm. (Sem. I) Examination

January - 2020

Product Development & Technology Transfer : MQA - 104T

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

1 Answer the following questions : **20**

(1) Define new drug as per CDSCO guideline.

(2) What is IND? What it contains and where it is to be submitted ?

(3) What FDA doesn't regulate ?

(4) What are review time frames and filing time frames in NDA regulation ?

(5) Why do we need post- marketing surveillance ?

(6) Write different criteria for selection of packaging materials.

(7) Classify different types of packaging materials with example.

(8) What is importance of quality control test in pharmaceutical packaging ?

(9) Discuss layout of pilot plant scale up study.

(10) How cosmetics are regulated by FDA?

2 Answer the following questions : (any **two**) **20**

(1) Enlist various ANDA certification clauses. Discuss in detail about para IV.

(2) Write classification of drugs in NDA. Draw flow chart of NDA submission.

(3) Write an informative note on solubility parameters that influence the preformulation study.

3 Answer the following questions : (any **seven**) **35**

(1) Discuss Hatch-Waxman amendment. What are its benefits?

(2) Enumerate various centres run by FDA. Write an informative note on CFSAN.

(3) Discuss different methods of post marketing surveillance.

(4) Discuss enteral and aseptic packaging system.

(5) Discuss quality control tests for glass and plastic containers.

(6) What SUPAC guideline defines ? Discuss about SUPAC-IR.

(7) Discuss different steps involved in technology transfer and product development.

(8) Enumerate the method for preparation of solid dispersion system and also explain in detail.

(9) Discuss different techniques for the study of crystal properties and polymorphism.
