DBW-014-1102001 Seat No. _____

M. Pharm. (Sem. II) (Regulatory Affairs)

(W.E.F. 2017) Examination

July - 2022

Regulatory Aspects of Drugs & Cosmetics : MRA-201T

Faculty Code : 014
Subject Code : 1102001

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

Instructions : (1) Figures to the right indicate full marks.
(2) Draw neat and clean diagram wherever required.

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

(1) What is Active Substance Master File ?
(2) Give the full form of SNDA, FFDCA, PANDRH and ASEAN.
(3) Enlist content of IMPD as per EU.
(4) What is Rest of the World Market ? Describe in brief with its classification.
(5) What is CEP ? Describe in brief.
(6) What is 180 day exclusivity ?
(7) What does qualified person mean in EU ? Enlist his/her duties.
(8) Give the name of any 6 CFRs given by USFDA.
(9) What are the regulatory authorities of Canada, South Korea, Saudi Arabia and Australia ?
(10) What is purple book ?

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

(1) Explain in details about the Hatch Waxman act, its procedure and loopholes.
(2) Write a note on Drug Master File.
(3) Describe the details about different types of NDA applications and its approval process in US.

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

(1) Describe the post marketing surveillance of drugs in Japan.

(2) Write down the organizational structure of PMDA.

(3) What are the differences between CTD and ACTD ?

(4) Write a short note on APEC and EAC.

(5) What are Cosmetics ? Explain in details about the Federal Register.

(6) Write a brief note on changes to an approved NDA/ANDA.

(7) Give the details note on Orphan Drug Regulations as per USFDA.

(8) Enlist names of CIS countries. Explain the legislations of drugs in brief in any one of the same.

(9) Write a brief note on COPP.