J-MPH-104-T Seat No. _____

M. Pharm. (Sem. I) Examination

January – 2020

Regulatory Affairs : MPH-104 T

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

(a) What is ANDA? Describe in brief different paras under 505(j) for the same.

(b) What is CFR? Describe below CFR are given for ?
(1) 21 CFR 201
(2) 21 CFR 314

(c) Differentiate API CMC and FPP CMC requirements.

(d) Enumerate methods by which generic drug entry can be delayed.

(e) Enlist any 8 guidelines with their numbers given by ICH ?

(f) What is Pharmacovigilance? Describe in brief.

(g) Write down the fullforms of MFR, BMR, DMF and HIPPA ?

(h) Write down the name of regulatory authorities of India, UK, Australia and Brazil countries.

(i) Which guidelines are available for Pharmaceutical Development and Common Technical Documents in ICH ?

(j) What is IMPD ? Describe in brief.

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

(a) Describe in brief about Drug price competition and patent term restoration act.

(b) Write a note on NDA Requirements and approval process.

(c) Write a descriptive note on SUPAC.

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

(a) Write a short note on types of DMF.

(b) Write a note on Common Technical Document.

(c) Describe in brief about Roles and Responsibilities of IRB/IEC.

(d) Classify ROW Countries and describe in brief about MHRA.

(e) What is ICH? Describe in brief its organizing structure and advantages to the industries.

(f) Explain in detail about Master Formula Record.

(g) Describe in brief about EMEA.

(h) Discuss about Informed Consent process.

(i) Enlist the things covered in clinical trial protocol and IB.