15/2/2023

Total No. of printed pages = 2

MPH 104 T

Roll No. of candidate | | | | | | | | | | |

2023

M.Pharm. 1st Semester End-Term Examination

REGULATORY AFFAIRS (THEORY)

(New Regulation)

Full Marks – 75 Time – Three hours

The figures in the margin indicate full marks for the questions.

1. Answer *all* the questions : (10 × 2 = 20)

   (a) How patent and generic drug products are related?

   (b) Differentiate between emergency IND and treatment IND.

   (c) What is the significance of regulatory affairs?

   (d) Enlist the drug regulatory agencies in USA, India, Australia and Europe.

   (e) Write the contents of the drug master file.

   (f) What is an institutional review board?

   (g) What are the different aspects of ICH?

   (h) What is CFR?

   (i) What do you mean by regulated countries and ROW countries?

   (j) What is the orange book?

2. Answer any *seven* questions : (7 × 5 = 35)

   (a) Explain the significance of the Hatch – Waxman Act.

   (b) Elaborate on the role and responsibilities of institutional review boards / independent ethics committees in clinical trials.

   (c) Write in detail about the investigator brochure.

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(d) Describe the pharmaceutical distribution system in India.

(e) HIPAA and its usefulness in clinical trials.

(f) Describe various activities of CRO in detail with suitable examples.

(g) Describe post-approval changes in approved ANDA.

(h) What is MFR? Describe the contents of MFR.

(i) Explain the In vitro drug product performance.

3. Answer any *two* questions : (2 × 10 = 20)

(a) Explain the global submission of NDA and ANDA.

(b) Give a detailed account of documentation in pharmaceutical industries with suitable examples.

(c) Write in detail about developing clinical trial protocols and other working procedures for conducting clinical trials.