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MD-MPH-104-T

Seat No. _____

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

January - 2018

MPH - 104 T : Regulatory Affairs

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

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

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

(a) Differentiate between IND, NDA and ANDA.

(b) Enlist four different regulatory agencies of different country for food and drug regulations.

(c) Give importance of informed consent form in clinical studies.

(d) State importance of post marketing surveillance in pharma industries.

(e) Define generic drugs.

(f) Enlist different toxicological studies need to be performed for IND submission.

(g) Define biologics and API.

(h) Differentiate MFR and BMR.

(i) What are combination products?

(j) Define dossier.

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

(a) Describe in detail CTD and ECTD recruitments for NDA and ANDA

(b) Describe different components of Master Formula Record.

(c) Explain the following :

(a) Clinical trial protocol;

(b) Institutional review board/independent ethics committee.

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

(a) Write a note on Hatch - Waxman act and amendments.

(b) Write a note on quality guideline prescribed by ICH.

(c) Write a note on HIPAA.

(d) Describe importance of pharmacovigilance.

(e) Describe in detail investigation medicinal products dossier.

(f) Explain : Investigator Brochure (IB)

(g) Explain and state the role of CFR in pharmacy.

(h) Describe different regulatory requirements for IND submission.

(i) Describe different requirement of SUPAC.

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