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PN-MPH104T Seat No. _____

M. Pharm. (Sem. I) Examination

July - 2018

MPH - 104T : Regulatory Affairs

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

Instructions : (1) Figures to the right indicate marks.

(2) Draw neat and clean diagrams as required.

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

(1) What do you mean by BE?

(2) Enlist different regions of ICH.

(3) Give full form of ICH.

(4) Give differences of IND, NDA and ANDA.

(5) Briefly describe post marketing surveillance.

(6) Give importance of distribution records.

(7) Briefly describe master formula record.

(8) Name the regulatory agencies of following countries : India, Europe, Canada and Australia.

(9) What is the role of CFR?

(10) Give full form of IMPD.

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

(1) Write a note on clinical trial protocols.

(2) Write a note on CTD and eCTD.

(3) Write a note on NDA.

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

(1) How Hatch - Waxman act and amendments effects generic drug market in US ?

(2) Write a note on ICH - M guidelines.

(3) Describe in detail regulatory requirements of Biologics.

(4) Describe in detail drug master file.

(5) Describe different stages of SUPAC.

(6) Write a note on HIPAA.

(7) Write a detailed note on Investigator Brochure (IB).

(8) Write a note on pharmacovigilance safety monitoring in clinical trials.

(9) What is the role of CMC in CTD?
