Q.6 Explain the steps involved in carrying out a clinical trial. Write the responsibilities and functional modalities for institutional review board.

Q.7 Write a detail note on Generic drug user fee amendments (GDUFA).

Q.8 Write short notes (Any Two)

(a) Clinical trials

(b) CMC

(c) ECTD format

(d) CTD format

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[Total No. of Questions: 8] *[Total No. of Printed Pages : 2]*

Enroll No……...…...……

MPH-104T

M. Pharm. (P'Ceutics)–I Semester (Reg./Ex) Examination, March-2021

Regulatory Affairs

Time: Three Hours

Maximum Marks:75

Note: Attempt any five questions. (Each question carries equal marks)

Q.1 How to handle Documentation in Pharmaceutical industry? Explain Generic drugs product development, Introduction Hatch-Waxman act and amendments?

Q.2 Write in detail the developing of clinical trials protocols and other working procedures for conducting the clinical trials.

Q.3 Explain documentation post marketing surveillance, outsourcing BA and BE to CRO?

Q.4 Write in detail CMC, post approval regulatory affairs and explain Regulation for combination products and medical devices, CTD and ECTD format?

Q.5 Explain the Invitro drug product performance and its limitations.