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Total No. of printed pages = 3

MPH 104 T

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

2019

M. Pharm 1st Semester End-Term Examination

REGULATORY AFFAIRS

(New Regulation)

(w.e.f. 2017-2018)

Full Marks – 75 Time – Three hours

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

GROUP – A

1. Answer any TEN questions (10 × 2 = 20)

   (a) Explain new drug applications (NDA) with respect to clinical trials.

   (b) Write notes on ANDA for generic drugs.

   (c) Differentiate Active pharmaceutical Ingredients (API) and Biologics.

   (d) Differentiate document and records.

   (e) What do you mean by institutional review board?

   (f) What do you mean by post marketing clinical trials?

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(g) Explain about minimum retention period of SOP and STP.

(h) What do you mean by MHRA and TGA?

(i) What do you mean by safety monitoring process?

(j) Mention four post approval studies with their requirement.

(k) Three assigned center for regulation in US-FDA mention.

GROUP – B

Answer any SEVEN questions

2. What do you mean by CMC? Briefly explain about the combination product and medical device as per regulation. (5)

3. Explain the following (2 + 3)

   (a) Pre NDA meeting

   (b) US registration for foreign drugs.

4. What do you mean by industry FDA liaison? Explain speed drug approval process through FDA initiatives. (5)

5. Explain the following (2.5 + 2.5)

   (a) CANA Guidance

   (b) HIPAA Privacy rule.

6. What do you mean by general FDA approval and post approval requirements biological for drug products? (5)

7. Draw a flow chart of pharmaceutical distribution system in India. (5)

8. Enumerate and justify the ethical consideration of clinical trials. (5)

9. Briefly explain about ICH Q, S, E, M regulatory requirements. (5)

10. What do you mean by outsourcing BA and BE to CRO? (5)

11. Explain following (2.5 + 2.5)

    (a) Row countries

    (b) ECTD format.

GROUP – C

Answer the following questions (any TWO)

12. What is global submission of IND, NDA, and INDA? Explain briefly about the investigation procedure dossier IMPD and investigator brochure. (10)

13. What are the different provision drawn under Hatch Waxman acts for the well being of innovator and justify code of federal regulation? (10)

14. What are the reasons for out sourcing of clinical trials? What are the roles of various regulatory agencies involved for clinical research regulation in India? (10)