Total No. of printed pages = 2

MPH 104 T

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

2021

M.Pharm. 1st Semester (Regular) Examination

Pharmaceutics

REGULATORY AFFAIRS

(New Regulation) (W.e.f. 2017-18)

Full Marks – 75 Time – Three hours

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

GROUP – A

1. Answer the following questions : (10 × 2 = 20)
   (a) What is the importance of drug master file?
   (b) What is the minimum retention period of STP?
   (c) Full form of ANDA and NDA.
   (d) How DMF filled?
   (e) What do you mean by institutional review board?
   (f) What do you mean by code of federal regulation?
   (g) Write the importance of post marketing surveillance.
   (h) How batch production records are documented?
   (i) What do you mean by safety monitoring process in pharmacovigilance?
   (j) Mention four post approval studies with their requirement?

GROUP – B

Answer any SEVEN questions.

2. 21 CFR part 210, part 211, and part 212 deals with what explain. (5)
3. Describe different phases of clinical trial (5)
4. Write the WHO Guideline on the drug distribution and documentation? (5)

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5. Briefly explain about CANA Guidance. (5)

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

7. Explain all about Pre NDA filling.

8. Write the comparison on regulatory process involved in generic drug approval process in USA, Europe and India? (5)

9. Write the importance of pharmaco-vigilance in of clinical trials? (5)

10. Briefly explain about Investigator brochure. (5)

11. What do you mean by out sourcing BA and BE? (5)

GROUP – C

Answer the following questions (Any *two*)

12. What are the provision drawn under Hatch Waxman act for generic manufacturer and consumer? (10)

13. Explain following ($2 \times 5 = 10$)

    (a) US registration for foreign drugs

    (b) QSEM Regulatory requirement

14. What are the reason for out sourcing in clinical trials? Write advantages and disadvantages in outsourcing?