Total No. of printed pages = 2

MPH 104 T

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

2022

M.Pharm. 1st Semester End-Term Examination

Pharmaceutics

REGULATORY AFFAIRS (THEORY)

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

Full Marks – 75 Time – Three hours

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

I. Answer *all* the questions : (10 × 2 = 20)

1. What do you mean by 21CFR part 314?

2. Outline the difference between IND, NDA and ANDA.

3. What is the importance of orange book?

4. What is the Drug Regulatory body in India and USA?

5. What is dossier in Drug Regulatory Affairs?

6. How distribution records benefit regulatory affairs?

7. What is Investigator brochure?

8. Explain the importance of Pharmacovigilance safety monitoring in clinical study?

9. Why drug regulatory affairs have the importance?

10. Differentiate between Generic drug product and innovator drug product?

[Turn over

II. Answer *any seven* questions : (7 × 5 = 35)

11. Write in detail about Post marketing surveillance.

12. Write a note on regulatory requirements of MHRA.

13. Explain about CTD and ETCD format and its usefulness in regulatory affairs.

14. What is the utility of Hatch Waxman Act.

15. Briefly describe about managing changes during post approval stages.

16. Discuss various aspects of CRO in detail with suitable examples.

17. Explain in detail about regulatory requirements for product approval for generic product.

18. What are the contents of Drug Master File (DMF).

19. Explain the Invitro drug product performance and its limitations.

III. Answer *any two* questions (2 × 10 = 20)

20. What are Clinical trials? Explain the regulatory guidelines of the documentation, clinical study design with respect to various phases involved in clinical trials. (2+8)

21. Describe the regulatory requirements for ICH guidelines with special reference to ICH-Q, S, E, M. (10)

22. Discuss the following: (5 + 5)

    (a) NDA regulatory approval process.

    (b) Active pharmaceutical ingredients and its specifications.
