MPH-104T

Roll No. | | | | | | | | | | |

ODD SEMESTER EXAMINATION 2022-23
COURSE NAME: M. PHARMA
SEMESTER: I
SUBJECT: REGULATORY AFFAIR

TIME: 3 HOURS MAX MARKS:75

NOTE: Attempt all parts.

PART A

(QUESTION NO. 1TO 10 ATTEMPT ALL QUESTIONS)(2x10)

1. When Hatch and Waxman act was made……..

2......are the committees related to EU Regulation

A) TGA

B) CDER

C) CBER

D) COMP

3. The FDA regulation is announced under the term of……..

4. Which Module of CTD include administrative and prescribing information……

5. By whom ANDA is reviewed, once it is acceptable……

6. Which type of DMF deals with manufacturing site…….

7. As per ANDA requirement, the bioequivalence of test to reference formulation is

A) 80-120%

B) 100-150%

C) 70-80%

D) 70-150%

8. API stands for……

9. A competitor can file for ANDA before its expiry under _____ clause of ANDA certification clause

A. Para I

B. Para II

C. Para III

D. Para IV

10. The guidelines for good manufacturing practice in India is

A. 21 CFR Part 4

B. Schedule M

C. 21 CFR Part 211

D. Eudralex Volume 4

PART B

(QUESTION No. 11TO13ATTEMPT ANY 2)(2x10)

11. Explain how a clinical trial is developed and discuss the working procedure of Clinical trial.
12. Give an account on significance of Hatch and Waxman act and elaborate its amendments.
13. "The performance of drug product is evaluated or improved using both in vivo and in vitro comparison assessment as key metrics." Analyze the logic behind above assertion.

PART C

(QUESTION NO. 14 TO 22 ATTEMPT ANY 7) (7x5)

14. Who formed CPSEA? Enlist some guidelines, objective and function of CPSEA.
15. Contrast between universal test/criteria & specific test/criteria of Q6 A guidelines or Distinguish between CBER & CDER.
16. Illustrate all of the BMR content & display the front-page format, which includes supersedes date, revision number and other information.
17. Define MFR. Enlist some general guidelines/instructions while preparing MFR.
18. With reference to packaging and labeling activities, specify line clearance and demonstrate reconciliation of printed packaging material.
19. Enlist the ICH Q series guidelines & summarize ICH guidelines Q3B (R2) for impurities in new drug product.

20. Prepare a flowchart that follows the ICH Q6 A guidelines for establishing acceptance criteria for degradation in new drug products.
21. How to minimize mix up and cross contamination in manufacturing operation and controls.
22. Elaborate the concept of QA & QC.