MQA-103T

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

ODD SEMESTER EXAMINATION 2022-23

COURSE NAME: M. PHARMA

SEMESTER: I

SUBJECT: QUALITY CONTROL & QUALITY ASSURANCE

TIME: 3 HOURS MAX MARKS:75

NOTE: Attempt all parts.

PART A

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

1. QMS, TQM, and QIP all corresponds to –

A. Quality techniques

B. Quality abbreviations

C. Quality parameters

D. None of the above

2. To Approve or reject the starting materials, packaging materials, and intermediate, bulk and finished products is responsibility of which department?

A) QC

B) QA

C) Production

D) All

3. Which type DMF deals with Manufacturing Site……

4. cGMP regulations for pharmaceutical manufacturing comes under which organization domain of US FDA

A. Center for Biologics Evaluation and Research

B. Center for Food Safety and Applied Nutrition

C. Office of Regulatory Affairs (ORA)

D. Center for Drug Evaluation and Research (CDER)

5. The scope of sanitation and hygiene covers-

A) Personnel

B) Premises

C) Equipments

D) All

6. The objective of FDA- India office is-

A). To ensure the safety, quality, and effectiveness of medical products and foodproduced in India for export to the United States.

B) Approval of medical products for marketing in India

C) Import of drug in India for test and examination

D) Manufacture of drugs in USA for the purpose of export to India

7. When the copyright act was passed…….

8. PIC was established in……

9. GMP ensures which of the following Parameters.

A) Quality

B) Safety

C) Efficacy

D) All

10. CDER & CBER stands for…….

PART B

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

11. Elaborate the three-tier documentation procedure in pharmaceutical industry and enlist the requirements for sanitization and hygiene in GMP.
12. Outline the QC test of tablet and capsule during production and at the end of the process.
13. Demonstrate about ICH M4 Guidelines and summarise about M4Q (R1) & M4Q (R2) for registration of pharmaceutical for human use.

PART C

(QUESTION NO. 14 TO 23 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.