Question Paper

Exam Date & Time: 30-Nov-2023 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences
BPharm Semester VII - End Semester Examination, November 2023

Date: 30-11-2023

Industrial Pharmacy II [PCE-BP702T]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) SUPAC stands for: (1)

- Scale up and post administrative channel.
- Scan up and post approval changes.
- Scale up and post approval changes.
- Scale up and pre-approval changes

2) The level of changes may impact on formulation and quality performance that unlikely to have detectable Impact is (1)

- Level 1
- Level 2
- Level 3
- Level 4

3) SUPAC SS refers to _____ (1)

- Changes in sterile formulations
- Changes in non-sterile semisolid formulations
- Changes in solid formulations
- Changes in suppository formulations

4) The purpose of utilizing platform technology in the pharma industry is : (1)

- To develop specialized drugs for rare diseases.
- To reduce cost of the drug development.
- To improve the drug manufacturing process.
- To enhance marketing strategies.

5) Following statement is True regarding the information to be provided during the Technology Transfer. (1)

- SU should provide a detailed characterization of the product, including its qualitative and quantitative composition
- SU need not provide any information on the history of process development
- SU need not provide Information on clinical development
- RU should provide the number and disposition of batches manufactured, and deviation and change control to SU

6) Pharmaceutical Quality System guidelines are given in (1)

- ICH Q9
- ICH Q10
- ICH Q11
- ICHQ12

7) A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. (1)

- Change Control
- Quality Control
- Quality Assurance
- All of the above

8) Documented verification that the equipment or system operates consistently and gives reproducibility within defined specifications and parameters. (1)

- Operational qualification
- Performance qualification
- Installation qualification
- Design qualification

9) For parenteral products manufacturing the following clean room facility must be used (1)

- Class 100 or 1000
- Class 10000 only
- Class 100000 only
- None of the above

10) Mark the era in which the Government has passed the Poisons Act: (1)

- 1990-1960
- 1880-1920
- 2000-2010
- 1990-1940

11) The role of the Clinical Trial Registry-India (CTRI): (1)

- To perform *in vivo* studies on animals.

- To perform audits in pharmaceutical companies.
- To register and conduct clinical trials in India.
- To conduct post marketing surveillance.

12) The Regulatory authority related to the UK country is: (1)

- Food and Drug Administration (FDA).
- Ministry of Health, Labor, and Welfare.
- Medical devices agency.
- Medicines and Healthcare products Regulatory Agency.

13) Phase IV of the Clinical Trial is related to: (1)

- Checking of safety profile in animals.
- Checking of efficacy in humans.
- Checking of adverse drug reaction in animals and volunteers.
- FDA review with safety surveillance.

14) The recent addition to the Hatch-Waxman Act includes: (1)

- non-extension of 40-month period.
- time limit for informing patent owner.
- Benefit of exclusivity for several INDs filed on the same allowed.
- Both a and c

15) Types of drug properties that can be considered for NDA filing (1)

- new molecular entity
- new combination of two or more drugs
- same salt of same existing drugs
- Both a and b

16) ANDA submits the para certifications under: (1)

- Section 505(k)(A)
- Section 21 CFR 313.95
- Section 22 CFR 314.95
- Both a and c

17) The ISO standard for Environmental Management Standards in production environment is: (1)

- ISO 7001
- ISO 9000
- ISO 9126
- ISO

14000

18) NABL is (1)

National Accreditation Board for Laboratories
National Accredited Board for Testing and Calibration Laboratories
National Accredited Board for Laboratories
National Accreditation Board for Testing and Calibration Laboratories

19) Certificate of Pharmaceutical Product is intended for: (1)

registration of the product.
licensing of the product
post-marketing of the product
Both 1 and 2.

20) Code of federal regulation title _____has provided a brief description for NDA and ANDA (1)

21 section 314 (21 CFR 314)
22 section 314 (22 CFR 314)
21 section 313.2 (21 CFR 313.2)
21 section 316 (21 CFR 316)

II Long Answers

Answer all the questions.

1) Discuss pilot plant scale up consideration for solids dosage solids. (10)

2) Discuss on granularity of technology transfer process. (10)

III Short Answers

Answer all the questions.

1) What is platform technology? Discuss the scope of WHO guidelines on technology transfer in pharmaceutical manufacturing. (5)

2) Define NDA and its objectives. What are the types of drugs that can be considered for NDA filing? (5)

3) Define Patent exclusivity under Hatch-Waxman Act. How is this exclusivity analyzed by the applicant for filing of the drugs? (5)

4) The assay of a tablet batch was found to be 92% and is outside the specification criteria (Specification 99-101%). Discuss the steps involved in the investigation. (5)

5) Define and enlist the Quality by Design (QbD) elements with respect to parenteral products. (5)

6) Explain the key responsibilities of RA professional in the management of Regulatory landscape. (5)

7) Explain the inclusion and exclusion criteria that are needed to be considered as a part of research clinical protocols. (5)

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