Question Paper

Exam Date & Time: 29-Dec-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 - S3]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) 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.

2) Detailed information concerning a specific facility, process or product submitted to the medicine's regulatory authority, intended for incorporation into the application for marketing authorization. (1)

- Finished pharmaceutical product detail
- In-process control
- Drug master file
- Validation protocol

3) Following is the example for Level I Change (1)

- Change to equipment of different design and principle
- Alternate equipment of the same design
- Changes in the type of process used
- All of the above

4) Reasons for technology transfer include (1)

- Lack of resources to launch product commercially
- Utilization in a different field of application
- Lack of marketing and distribution capability
- All of the above

5) Following statement is NOT TRUE (1)

- Technology transfer does not include the patentable aspects of production
- Technology transfer includes the business processes, such as knowledge and skills.
- Technology transfer helps to achieve standardized process which facilitates cost effective production.
- Technology transfer is the transfer of any process together with its documentation and professional expertise.

6) A planned set of controls, derived from current product and process understanding, that assures process performance and product quality. (1)

- Confirmation testing
- Change Control
- Control strategy
- None of the above

7) Analytical methods transfer protocol should include (1)

- Only a description of the objective, scope and responsibilities of the SU
- Only a description of the objective, scope and responsibilities of the RU
- A description of the objective, scope and responsibilities of the SU and the RU
- None of the above

8) Documented verification that the system or subsystem performs as intended over all anticipated operating ranges. (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) In Para IV certification, an original patent holder can sue ANDA applicant within _____ (1)

- 45 days
- 20 days
- 15 days
- 35 days

11) The term of patent is valid for the period of 20 years from the (1)

- Date of approval
- Date of examination
- Date of publication
- Date of filing of application

12) In 1970, FDA established _____as a mechanism for the review and approval process of generic versions (1)

- IND
- NDA
- ANDA
- IND and ANDA

13) Module 3 of the e-CTD triangle mainly works with the (1)

- pharmacological, pharmacokinetics and toxicological evaluations
- safety, efficacy, and quality evaluations
- both 1 and 2, depending upon the regional geographic conditions
- chemistry, manufacturing, and control of biologic drugs

14) Hatch-Waxman act framework includes: (1)

- Approve manufacturing of sutures and ligatures.
- Streamlining the process for branded pharmaceuticals products.
- Streamlining the process of generic pharmaceutical approvals.
- Approve medical devices.

15) Identify the relevant regulatory body in USFDA for approval of drugs: (1)

- BLA
- IND
- NDA
- CDER

16) Define product patent: (1)

- Exclusive right is given to the original inventor of a product
- Exclusive right is given to protect the new drug entity
- Exclusive right is given to the applicant for pilot scale up
- Exclusive right is given to the applicant for filing a drug dossier

17) ISO 9003 is (1)

- Quality Systems - Model for Quality Assurance in Final Inspection and Test
- Quality Systems - Model for Quality Assurance in Production and Installation

Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing

Quality Management and Quality System Elements - Guidelines

18) Analysis of the original, homogenous sample material is (1)

Retesting

Resampling

Averaging

Outlier

19) Animal studies, clinical trials, bioavailability studies are part of which application process (1)

IND

NDA

ANDA

BLA

20) cGMP regulations for pharmaceutical manufacturing comes under which organization domain of US FDA (1)

Centre for Biologics Evaluation and Research

Centre for Food Safety and Applied Nutrition

Office of Regulatory Affairs (ORA)

Centre for Drug Evaluation and Research (CDER)

II Long Answers

Answer all the questions.

1) Discuss the general factors to be considered in pilot plant scale up technology. (10)

2) Discuss various phases of a technology transfer project. (10)

III Short Answers

Answer all the questions.

1) What is the purpose of SUPAC guidelines? Write the significance of cleaning method transfer during technology transfer. (5)

2) Point out the differences between NDA and ANDA. Discuss the various forms of NDA and their relevance. (5)

3) Define Patent and Patent Infringement. Discuss the different types of Para Certifications. (5)

4) Explain the influence of cost of quality in pharmaceutical product development. (5)

5) Define and enlist the Quality by Design (QbD) elements with respect to tablet product development. (5)

6) Explain the roles, responsibilities, and functions of CDSCO. (5)

7) Define bioavailability and bioequivalence. Discuss the NDA and ANDA requirements for RLD and generic drugs. (5)

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