Final y. B. Pharm
Sem – VII
26/11/2025

Duration: 3 Hours **Total marks: 75**

N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks.

Q.I Multiple Choice Questions **20M**

1 Which of the following is the responsibility of pilot plant team?

a) Equipment selection

b) Staff selection

c) Design of promotional brochure

d) Patent application

2 Which factor is critical during scale-up of tablets?

a) Selection of bottle filling machine

b) Score marks on the tablet

c) Color of the tablet

d) Selection of Dryer

3 SUPAC guidelines are applicable for the changes -

a) During Research & development

b) In Pilot plant studies

c) After product is marketed

d) In the patent application

4 Which of the following is an example of a platform technology?

a) Dry granulation

b) Nanoparticles

c) Tablet compression

d) Soft gelatin capsules

5 SUPAC stands for-

a) System Utilization and Pre Marketing Application Changes

b) Scale Up and Pre Marketing Application Changes

c) Scale Up and Post Marketing Approval Changes

d) System Utilization and Post Marketing Approval Changes

6 **What is the primary objective of technology transfer in the pharmaceutical industry according to WHO guidelines?**

a) To ensure consistent product quality and regulatory compliance

b) To reduce production costs

c) To improve packaging design

d) To increase marketing reach

7 **Which phase of Tech Transfer involves the assessment of the receiving unit's capability to manufacture the product?**

a) Clinical Trials

b) Process Validation

c) Analytical Method Transfer

d) Feasibility Study

8 **Responsibility of successful technology transfer lies with**

a) The receiving unit

b) The sending unit

c) Both sending and receiving units

d) WHO

9 **The preparation of Master Packing Card is done in**

a) Research Phase

b) Development Phase

c) Production Phase

d) Analytical Method Transfer phase

10 **Which CTD Module contains both Nonclinical Overview and Clinical Overview information ?**

a) Module 2

b) Module 3

c) Module 4

d) Module 5

11 Which part of the Investigator's brochure contains Pharmacological and Toxicological information?

a) Summary

b) Non-clinical Studies

c) Clinical Studies

d) Safety information

12 Which document is submitted to obtain approval for human clinical trials?

a) NDA

b) IND

c) DMF

d) ANDA

13 CDSCO (Central Drugs Standard Control Organization) is the national regulatory Authority of which country?

a) India

b) USA

c) Australia

d) Japan

14 The main role of regulatory professionals is to

a) Design drug molecules for CMC

b) Prepare and submit FDA approval documents

c) Conduct Clinical Trials for IND

d) Conduct Preclinical Trials for IND

15 In Six Sigma, "DMAIC" stands for

a) Develop, Monitor, Adjust, Implement, Control

b) Determine, Manage, Adjust, Improve, Correct

c) Define, Measure, Analyze, Improve, Control

d) Design, Manage, Act, Inspect, Control

16 **ISO 9000 series primarily deals with**

a) Environmental management

b) Laboratory accreditation

c) Product management

d) Quality management systems

17 **Which of the following is a key principle of Good Laboratory Practice (GLP)**

a) Use of uncertified instruments

b) Documentation and traceability

c) Data deletion after analysis

d) Informal reporting

18 **The Drugs Controller General of India (DCGI) functions under**

a) WHO

b) CDSCO

c) MHRA

d) EMA

19 **The Drugs and Cosmetics Act was passed in which year?**

a) 1940

b) 1950

c) 1960

d) 1965

20 **The Common Technical Document (CTD) format, under ICH M4, is used for**

a) Compiling Quality, Safety, and Efficacy data

b) Compiling Packaging and Quality Data

c) Compiling Manufacturing and Efficacy Data

d) Compiling Validation and Safety Data

QII Answer the following (any two) **20**

1 a) Define the levels of change as per SUPAC guidelines and give requirements of documents for each one. **6**

b) What are the advantages of Platform Technology? Explain in brief any one type of platform technology. **4**

2 Specify the roles and responsibilities of SU and RU in Tech Transfer. Explain the contents and importance of Project Report **10**

3 Define IND. Elaborate in detail about General considerations of Investigational New Drug Application. **10**

QIII Answer the following (any seven) **35**

1 State the objectives of Pilot plant Study. Give composition of the team. **5**

2 What is the role of Tech Transfer Agencies? State the functions of any one agency. **5**

3 Elaborate on the role of documentation in Tech Transfer with suitable examples. **5**

4 Write the importance of Bioequivalence studies in Pharmaceutical Product Development. **5**

5 Discuss in detail the two phases of an Out of Specification (OOS) Investigation. **5**

6 Write a note on the concept and methodologies of Six Sigma. **5**

7 Elaborate on benefits and procedure of NABL Accreditation. **5**

8 Write a short note on Central drugs Standard Control of Organization (CDSCO). **5**

9 Elaborate in brief about COPP. **5**

X----------X----------X