MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
(A constituent unit of MAHE, Manipal)

BPharm Semester VII Make-up End Semester Examination January 2023

Course Code: PCE-BP702T Course Title: Industrial Pharmacy-II (Theory)

Date: 19/01/2023 Duration: 3 hrs Max. Marks: 75

Instructions: Answer ALL questions.

I Multiple Choice Questions (MCQs)	**20 Q × 1 mark = 20 marks**
CDSCO is related to A. Technology Transfer B. Production C. Regulatory requirements D. Quality-by-design	
Important component of technology transfer involves all of the following except A. Proper Research & paper work B. Pricing & publicity C. Partnership & People's Acceptance D. FDA's sanction	
Quality management system deals with …… A. Quality for their products and services B. Safety for their products and services C. Quality and safety for their products D. Quality and safety for their products and services	
Scale up batch size is usually -----of the commercial batch A. 1/3rd B. 1/2th C. 1/10th	

D. 1/100th

Which of the following is not a scale-up process?

A. Laboratory to pilot-scale

B. Pilot-scale to industrial-scale

C. Industrial to pilot-scale

D. Laboratory to industrial-scale

Identification of critical elements of a process which are available at the sending unit but are missing from the receiving unit.

A. Drug Master File

B. Gap Analysis

C. Corrective Action

D. In-Process Control

Quality control is defined as ……

A. Sampling and documentation

B. Sampling, specification and documentation

C. Sampling, specification, testing, documentation and release procedures

D. None of these

Carcinogenicity and Genotoxicity study is a …… aspect of ICH guidelines.

A. Safety guidelines
B. Efficiency guidelines
C. QSEM guidelines
D. All of these

Six sigma concept includes …….

A. Define, Measure, Analyze, Improve and Control

B. Design, Measure, Analyze, Improve and Control

C. Define, Manage, Analyze, Improve and Control

D. All of these

What does SDRA stands for

A. State Drug Regulatory Act

B. State Drug Regulatory Authorities

C. State Dosage Regulatory Act D. State Drug Regulatory Activity
DMF stands for A. Drug Master File B. Dossier Master File C. Drug Manufacturing File D. Dossier Manufacturing File
Pilot plant area consists of A. Physical testing area B. Equipment floor space C. Both of the above D. None of the above
Master manufacturing procedure consists of A. Chemical weigh sheet B. Sampling directions C. Both of the above D. None of the above
SUPAC stands for A. Scale Up and Post Approval Changes B. Scale Up and Pre Approval Changes C. Scale Up and Post Approval Considerations D. Scale Up and Pre Approval Considerations
GMP items in scale-up include: A. Equipment Qualification B. Process Validation C. Both of the above D. None of the above
Which unit operation is not there in tablet manufacture? A. Blending B. Milling

C. Granulating D. Encapsulation
CDSCO stands for A. Central Dossier Standard Control Organization B. Central Drugs Standard Control Organization C. Cumulated Drugs Standard Control Organization D. Cumulated Dossier Standard Control Organization
What is CRO? A. Contract Research Organization B. Central Research Organization C. Contract Regulatory Organization D. Central Regulatory Organization
NDA stands for A. Novel Drug Application B. New Drug Application C. Natural Drug Application D. Nano Drug Application
Indian Drugs and Cosmetics Act was passed in A. 1958 B. 1938 C. 1940 D. 1904

II Long Answers	**2 Q × 10 marks = 20 marks**
1. Define pilot plant scale. Write its importance. Describe any two considerations in pilot plant scale-up.	
2. Discuss in detail about Central Drug Standard Control Organization	

III Short Answers	**7 Q × 5 marks = 35 marks**
1. Write a note on Indian regulatory requirements.	
2. What is regulatory affairs? What are the responsibilities of regulatory affairs professional in a formulation manufacturing company.	
3. Name the drug regulatory authorities of five geographies.	
4. What is the concept of TQM and their characteristics. Explain in detail various elements and importance of TQM	
5. Discuss in detail the Transfer of packaging materials.	
6. Explain Out of Specification (OOS) concept	
7. Elaborate Quality-by-Design (QbD) approach	