

**B. PHARM.  
SEVENTH SEMESTER  
INDUSTRIAL PHARMACY II  
BP702T [SPECIAL REPEAT]  
[USE OMR SHEET FOR OBJECTIVE PART]**

**SET  
A**

Duration : 3 hrs.

Full Marks : 75

**( PART-A: Objective )**

Time : 30 min.

Marks : 20

*Choose the correct answer from the following:*

*1×20=20*

1. ICH Q3 guideline for
  - a. Stability
  - b. Impurity
  - c. Validation
  - d. QRM
2. COPP is recommended by
  - a. WHO
  - b. CDSCO
  - c. State
  - d. None of the above
3. Self life of a drug is determined by
  - a. Stability study
  - b. Chemical analysis
  - c. Assay
  - d. Pharmacovigilance
4. Two or more drug products that contain the same labeled active ingredient and in same amount, is called
  - a. Chemical equivalence
  - b. Pharmaceutical equivalence
  - c. Bioequivalence
  - d. Therapeutic equivalence
5. ICH guidelines involve \_\_\_\_\_
  - a. Quality, Safety
  - b. Quality, Safety and efficiency
  - c. Quality control and multidisciplinary guidelines
  - d. Quality, Safety, efficiency and multidisciplinary guidelines
6. Which one is a focus of TQM?
  - a. Cost of product
  - b. Timeline
  - c. Customer focus
  - d. None of the above
7. Assay comes under \_\_\_\_\_
  - a. QTPP
  - b. CQA
  - c. QA
  - d. CQP
8. ICH Q7 for \_\_\_\_\_
  - a. Impurity
  - b. GMP
  - c. Stability
  - d. Pharmacopoeia
9. Full form of SUPAC?
  - a. Scale up and post approval changes
  - b. Scale down and post approval changes
  - c. Syrup and parental approval changes
  - d. None of the above

10. BMR is prepared by?
  - a. Production
  - b. R&D
  - c. QA
  - d. QC
11. Definition of Quality risk management has been mentioned in ICH guideline
  - a. Q7
  - b. Q8
  - c. Q9
  - d. Q3
12. Scale-up process performed by?
  - a. R&D
  - b. Technology transfer
  - c. Production
  - d. All of the above
13. Which department responsible for auditing pilot plant?
  - a. QA
  - b. QC
  - c. R&D
  - d. Production
14. Head of central drug testing laboratory-
  - a. Drug controller of India
  - b. Director general of health services
  - c. DCGI
  - d. None of the above
15. Form 10/10A for
  - a. Clinical trials
  - b. Permission to import new drugs
  - c. Permission to manufacture new drugs
  - d. Issue of import license
16. Rule 122A for
  - a. Clinical trials
  - b. Permission to import new drugs
  - c. Permission to manufacture new drugs
  - d. Issue of import license
17. ISO 14000 for
  - a. Environment responsibility
  - b. Accreditation body
  - c. Customer need
  - d. Both b and c
18. ICH Q8 for \_\_\_\_\_
  - a. Impurity
  - b. Pharmaceutical Development
  - c. Stability
  - d. Genotoxicity study
19. National regulatory authority of INDIA?
  - a. USFDA
  - b. CDSCO
  - c. MHLW
  - d. MHRA
20. 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 the above



**( PART-B :Descriptive )**

Time : 2 hrs. 30 min.

Marks : 35

*[ Answer any seven (7) questions ]*

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|--|---|
| 1. Define GLP. Write functions of CDTL.  | 5 |
| 2. Explain responsibility of Regulatory Affair Professional.                     | 5 |
| 3. What is TQM? Explain six sigma processes.                                     | 5 |
| 4. Define OOS, Change control and ISO. Write functions of CDSCO.                 | 5 |
| 5. Explain Investigator Brochure.  | 5 |
| 6. Discuss principle of QRM and Process.   | 5 |
| 7. What is SUPAC guideline? Write general requirements for pilot plant scale up. | 5 |
| 8. Define IND application? Explain different IND applications.                   | 5 |
| 9. Define Regulatory affair. Mention layout chart for IND application.           | 5 |

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**PART-C: Long type questions**

*[ Answer any two (2) questions ]*

1. What do you mean by pilot plant scale -up? What is its significance of pilot plant scale up with routine production procedure? Explain the critical aspects of solid and semi solid dosage form. 10
2. Define QbD. Explain objectives of QbD and elements of QbD. 10
3. Define QMS. Mention scopes of QMS. 10

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