3. Mention the basic role of SUPAC and write the levels of SUPAC IR guidelines. (2+3)
4. Briefly write the history and overview of Regulatory affairs. 5
5. Write the general consideration of IND application. 5
6. Write five key features of QbD in pharmaceutical industry. 5
7. Highlight five key roles of state licensing authority. 5
8. Highlight five features of OOS. 5
9. Highlight five key principles of GLP guidelines. 5

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UG Odd Semester (CBCS) Examination, 2022
held in March 2023

PHARMACEUTICAL SCIENCES

(7th Semester)

Course No: BP 702T

(Industrial Pharmacy II-Theory)

Full Marks: 75

Time: 3 Hours

The figures in the margin indicate full marks for the questions

I (A). Multiple choice questions 1x10=10

1. Scientists with experience in pilot plant operations as well as in actual production area are the most preferable for ____.
   a. Quality Control
   b. Quality Assurance
   c. R & D
   d. Pilot Plant
2. _____ is the art for designing of prototype using the data obtained from the pilot plant model.
   a. Production
   b. Pilot plant
   c. Scale up
   d. R & D
3. Which Batch is eligible for biostudy?
   a. Commercial Batch
   b. R & D Batch
   c. Pilot Batch
   d. Export Batch

(Turn Over)

4. Measurable terms under which a test result will be considered acceptable is called as _____.
   a. Bracketing
   b. Quality Assurance
   c. Quality Control
   d. Acceptance Criteria

5. Risk reduction focuses on the reduction of probabilities of occurrence and detection of _____.
   a. Hazard
   b. Harm
   c. Failed Batch
   d. Severity

6. Association of RA Professionals in India established in____.
   a. Oct, 1996
   b. Oct,2000
   c. Oct, 2006
   d. Oct, 2016

7. Who advices DCGI?
   a. DTAB
   b. DCC
   c. Both
   d. None

8. How many zonal office of CDSCO is there in India?
   a. 2
   b. 4
   c. 6
   d. 8

9. What does schedule Y of drug and cosmetics act 1940 and rules 1945 talk about?
   a. Pharmacovigillance
   b. Clinical Trials
   c. New Drug Approval
   d. Investigational New Drug

10. What ISO 14000 series talks about?
    a. Industrial Premise
    b. Manufacturing Cycle
    c. Shelf Life
    d. Environment Control

I (B). Objective type (Answer the following in brief) 2x5=10

1. Write the significance of Pilot plant.
2. What is the goal of Technology Transfer?
3. Write the components of Clinical trial protocol.
4. Write full form of COPP and SLA. 1+1
5. Write full form of DCGI and who is the current DCGI? 1+1

II. Long answers (Answer two out of three questions) 10x2=20

1. Draw the organizational structure of CDSCO. Highlight five key responsibilities of CDSCO. (5+5)
2. What is granularity in TT? Discuss transfer of technology for finished product. (3+7)
3. What is the basic principle of QRM? Describe an overview of typical quality risk management process. (2+8)

III. Short answers (Answer seven out of nine questions) 5x7=35

1. What is Platform technology? Write the benefits of platform technology. (1+4)
2. What is validation? Explain the types and stages of validation. (2+3)

(Turn Over)