Summer-2023
11/05/23

CJ-04

BP 702 T

INDUSTRIAL PHARMACY – II

P. pages: 1

Time: Three Hours

Max. Marks: 75

Instructions to Candidates:

1. Do not write anything on question paper except Seat No.
2. Graph or diagram should be drawn with the black ink pen being used for writing paper or black HB pencil.
3. Students should note, no supplement will be provided.
4. All questions are compulsory.
5. Draw neat & well labelled diagram wherever necessary.

20

1. Multiple Choice Questions.

1) Qualification is
[A] Regulatory requirement [B] Process based approach
[C] Verification of quality [D] Documented verification

2) Primary goal of phase 4 of clinical research
[A] Testing of drug on healthy volunteers for safety
[B] Testing of drug on patients to asses efficiency of side effects
[C] Post marketing surveillance [D] All the above

3) Clinical trials are
[A] Testing in humans [B] Testing in animals
[C] Study of ADME [D] Marketing phase

4) Technology transfer is_____
[A] Partial commercialization [B] Full scale Commercialization
[C] Both A&B [D] None

5) The basic requirement of technology transfer is
[A] Sending unit [B] Receiving unit [C] Both A&B [D] None

6) Pilot plant can be used for
[A] Evaluating results for laboratory studies [B] Product & process correction
[C] Both A &B [D] None

7) DCGI stands for
[A] Drugs Commissioner General of India [B] Deputy Commissioner General of India
[C] Drugs Controller General of India [D] None of the above

8) TT agencies in India
[A] APCTT [B] NRDC [C] TIFAC [D] All the above

9) The headquarter of CDSCO is located at
[A] New Delhi [B] Kolkata [C] Mumbai [D] Chennai

10) As per GLP reagents & solutions should be
[A] Labeled properly [B] Do not need to mention them in SOPs
[C] Stored in refrigerator [D] All the above

11) ISO 9004 contains
[A] Guidelines for the application of ISO 9000

[B] Guidelines for quality assurance [C]Guidelines for sustaining QMS
[D] None

12) Which of the following is certification system for laboratory accreditation?

[A] ISO [B] WHO [C] NABL [D] GMP

13) TQM is _____ oriented

[A] Personnel [B] Method [C] System [D] Procedure

14) _____is the regulatory authority of India

[A] EMEA [B] CDSCO [C] MPA [D] MHRA

15) The term scale up means

[A] Increasing batch size [B] Increasing production rate
[C] Both A&B [D] None

16) Full form of SUPAC

[A] Scale up & post approval changes [B] Scale up & post approval correction
[C] Scale up & periodic approval changes [D] Scale up & post assisted changes

17) Regulatory authority of Australia

[A] MHRA [B] TGA [C] CDSCO [D] USFDA

18) What is the vision of CDSCO ?

[A] To protect public health in India [B] To promote public health in India
[C] Both A&B [D] None

19) Full form of OOS

[A] Out of State [B] Out of Stock C] Out of Shadow [D] Out of Specification

20) _____provides the guidelines & requirements for clinical trials.

[A] Schedule Y [B] Schedule X [C] Schedule [D] Schedule P

2. Long Answer Questions Attempt any two. **20**

1)Define pilot plant. Explain the process of drug product development with the help of suitable diagram.

2)What do you mean by the term accreditation? Enlist scope & benefits of NABL Accreditation.

3)Explain in detail various functions perform by CDSCO.

3. Short Answer Questions Attempt any seven. **35**

1)Write short note on NRDC.
2) Write short note on SIDBI.
3)Discuss briefly different regulatory authorities.
4)Explain the approval procedure for new drugs.
5)Discuss briefly basic component of total quality management.
6)Define validation. Give the importance of validation .Enlist types of validation.
7)Describe the approach of QbD in quality management system.
8)Discuss confidentiality aggreement.
9)Write about common technical documents.