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Total No. of printed pages = 4

**BP 702 T**

Roll No. of candidate | | | | | | | | | | |



**2022**

**B.Pharm. 7th Semester End-Term Examination**

**INDUSTRIAL PHARMACY – II**

**(New Regulation)**

Full Marks – 75 Time – 3 hours

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The figures in the margin indicate full marks for the questions.

1. Multiple choice questions (MCQ) (Answer all questions) (20 × 1 = 20)

(i) Master formula card, master formula, specifications, development report parts of

(a) CTD (b) Technology Transfer report

(c) Technology Transfer dossier (d) DMF

(ii) Which is NOT a key element of TQM?

(a) Ethics (b) Trust

(c) Hard work (d) Teamwork

(iii) _____ filed before conducting the clinical trials

(a) ANDA (b) INDA

(c) NDA (d) None of the above

(iv) CDSCO is headed by

(a) DGHS (b) DCGI

(c) Health Minister State (d) Health Minister Central

(v) SUPAC guideline deals with

(a) Level of changes

(b) Filing documentation

(c) Recommend chemistry, manufacturing and control tests

(d) All of the above

[Turn over

(vi) Biowaiver is given to which of the following case

(a) Drugs are parenterally administered

(b) Drugs in solution form

(c) Drugs in gaseous form

(d) All of the above

(vii) Who guidelines for technology transfer are mentioned in which annexure of WHO technical report series 961,2011 of

(a) Annexure 9 (b) Annexure 5

(c) Annexure 7 (d) Annexure 4

(viii) Bioequivalence studies are not required in case of

(a) Drugs are parenterally administered

(b) Drugs in solution form

(c) Drugs in gaseous form

(d) All of the above

(ix) ISO 9000 series is mainly based on principle of

(a) Customer focus (b) Profit oriented

(c) Sale oriented (d) None of the above

(x) Which ICH guideline explain the process of QRM

(a) Q8 (b) Q9

(c) Q7 (d) Q6

(xi) Which of the following is not a unit of ToT

(a) Sending Unit (b) Receiving Unit

(c) Tertiary Unit (d) Unit managing the Process

(xii) After risk assessment and risk control what will be the next step?

(a) Risk evaluation (b) Risk review

(c) Risk Analysis (d) None

(xiii) Which of the following is a characteristic of ToT as per WHO

(a) It is systematic process

(b) It involves transfer of documents

(c) It involves transfer of knowledge gained through development process

(d) All of the above

(xiv) NABL is autonomous body under

(a) Department of Biotechnology (b) Good Laboratory performance

(c) General laboratory practice (d) General laboratory performance

(xv) Which one of the following is Tool/s of QRM

(a) FTA (b) HAZOP

(c) HACCP (d) All of the above

(xvi) Assessment of risk and controlling of risk are the steps under

(a) Quality risk management (b) Quality control

(c) Quality assurance (d) Validation

(xvii) Which of the following is not a TT team.

(a) Production (b) Engineering

(c) Regulatory affair (d) Designing

(xviii) The measurement of extent of absorption is known as

(a) Cmax (b) Tmax

(c) AUC (d) None of the above

(vix) Which of the following provides base for commercial-scale production?

(a) Pilot Plant (b) Scale up

(c) Trial Batch (d) All of the above

(xx) LD 50 stands for

(a) Legal dose 50 (b) Lethal Dose 50

(c) Legitimate dose 50 (d) None of the above

II. Short answers (Answer seven out of nine) $(7 \times 5 = 35)$

2. What is TQM? Explain the key elements of TQM.

3. What is Quality Risk Management? Explain QRM process.

4. What is bioequivalence studies? Describe in details.

5. Define ToT as per WHO and write the characteristics of ToT as per WHO.

6. What are the steps of technology transfer? Write the reason for technology transfer.

7. Elaborate the Sending unit and receiving unit.

8. What is SUPAC? Explain the different levels of changes under SUPAC guidelines.

9. Define pilot plant scale up? Explain the process of pilot plant scale up.

10. Write a not eon ISO 9000 series of quality systems standards.

III. Long answers (Answer any two out of three) $(2 \times 10 = 20)$

11. Explain Organization and management in details.

12. What is Six Sigma Concept? Write the characteristics and Objectives of Six Sigma.

13. Describe in detail general consideration for Investigational new drug application. Write a short note on Investigator's Brochure.

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