Total No. of printed pages = 4

# BP 702 T

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

**2023**

**B.Pharm 7th Semester End-Term Examination (Regular)**

**INDUSTRIAL PHARMACY – II**

Full Marks – 75 Time – Three 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) TQM is:

(a) Product oriented (b) Process oriented

(c) Customer oriented (d) Sale oriented

(ii) ISO 9000 was first published in

(a) 1986 (b) 1987

(c) 1988 (d) 1989

(iii) OOS stands for

(a) Out of statistics (b) Out of Scenario

(c) Out of specification (d) None of the above

(iv) CCSEA stands for:

(a) Committee for Care and Supervision of Experiments on Animals

(b) Committee for Control and Supervision of Experiments on Animals

(c) Committee for Control and Scanning of Experiments on Animals

(d) Consultancy for Control and Scanning of Experiments on Animals

(v) SUPAC guideline deals with ———— types of changes

(a) One (b) Two

(c) Three (d) Four

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(vi) The main objective of TQM is:

(a) Continuous improvement (b) Profit

(c) Controlling of process (d) All of the above

(vii) ANDA stands for:

(a) Analysed New Drug Application

(b) Approved New Drug Application

(c) Additional New Drug Application

(d) Abbreviated New Drug Application

(viii) MHRA is drug regulatory authority of:

(a) France (b) UK

(c) Belgium (d) Italy

(ix) ED 50 is:

(a) Essential dose 50 (b) Effective dose 50

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

(x) Which is NOT a key element of TQM

(a) Ethics (b) Controlling

(c) Team work (d) Leadership

(xi) QRM related guidelines in ICH

(a) Q7 (b) Q8

(c) Q9 (d) Q10

(xii) Safety guidelines of ICH are given in

(a) Q series (b) S series

(c) E series (d) M series

(xiii) SUPAC stands for:

(a) Scale-up and the pre-approval changes

(b) Scale-up and the post-approval changes

(c) Scale-up and the past-approval changes

(d) Scaling-up and the post-approval changes

(xiv) Safety toxicology data of CTD is present in

(a) Module 1 (b) Module 2

(c) Module 3 (d) Module 4

(xv) New drug approval in India is authorized by:

(a) CDSCO (b) CCSEA

(c) HACCP (d) All of the above

(xvi) GLP stands for:

(a) Good laboratory performance

(b) General laboratory practices

(c) Good laboratory phase

(d) Good laboratory practices

(xvii) Post marketing surveillance is done in clinical trial phase

(a) Phase 1 (b) Phase 2

(c) Phase 3 (d) Phase 4

(xviii) Non clinical study of drug is:

(a) Phase 1 study

(b) Pharmacokinetic and pharmacodynamic study

(c) ADR monitoring

(d) None of the above

(xix) Authorities involved in TOT?

(a) WTO and WIPO (b) ICH

(c) CDSCO (d) All of the above

(xx) Quality management systems requirements are mentioned in

(a) ISO 9001:2015 (b) ISO 9004:2018

(c) ISO 9000:2015 (d) None of the above

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

(a) What is the difference between NDA and INDA? Explain about the approval process of a new drug.

(b) Write in details about the Transfer of technology with reference to WHO guidelines for it.

(c) Discuss the concept of TQM with respect to its origin, principles, main objectives, advantages and disadvantages.

3. Short answers (Answer Seven out of Nine) (7 × 5 = 35)

(a) Give a note on different levels of changes under SUPAC guidelines.

(b) What do you mean by ISO? Give a brief note on ISO 9000 series.

(c) Write a note on Investigator's Brochure.

(d) Enumerate the importance and scope of QbD.

(e) What do mean by Regulatory affairs? Write the historical overview of Regulatory affairs.

(f) Explain the characteristics and objective of Six Sigma concept.

(g) What is GLP? Discuss its objectives and fundamentals.

(h) Write about the different operational aspects of pilot plant.

(i) What is QRM? Write its application in Pharmaceuticals.