Total No. of printed pages = 4

BP 702 T

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

2021

B.Pharm. 7th Semester End-Term Examination

Pharmacy

INDUSTRIAL PHARMACY-II (THEORY)

(New Regulation)

Full Marks – 75 Time – Three hours

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

1. Answer *all* the question.

Choose the most appropriate alternative for the following multiple-choice questions. (20 × 1 = 20)

(i) ISO stands for

(a) International standardization organization

(b) International statistical organization

(c) International organization for standardization

(d) International organization for statistics

(ii) Which "M" is **NOT** a part of 5 "M"s of plant?

(a) Management (b) Money

(c) Man (d) Machine

(iii) Which level of changed have the significant impact on the quality or performance of formulation

(a) Level 1 (b) Level 2

(c) Level 3 (d) Level 4

[Turn over

(iv) Which of the following is/are reason for conducting pilot-plant studies?

(a) Evaluation of results

(b) Determination of waste products

(c) Decision making

(d) All of the above

(v) Which is NOT a SUPAC guidance documents

(a) SUPAC-IR (b) SUPAC-MR

(c) SUPAC-SS (d) SUPAC-SR

(vi) SUPAC guideline deals with

(a) Level of changes

(b) Recommend chemistry, manufacturing and control tests

(c) Filing documentation

(d) All of the above

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

(a) CTD

(b) Technology Transfer report

(c) Technology Transfer dossier

(d) DMF

(viii) Assessment of risk and controlling of risk are the steps under:

(a) Quality risk management

(b) Quality control

(c) Quality assurance

(d) None of the above

(ix) APCTT headquarter is situated at:

(a) Delhi (b) Mumbai

(c) Bangalore (d) Chennai

(x) The success of technology transfer DO NOT depend upon

(a) Communication (b) Capacity

(c) Co-ordination (d) None of the above

(xi) Which of the following form is filed before conducting the clinical trials

(a) ANDA (b) INDA

(c) NDA (d) None of the above

(xii) Which is **NOT** a key element of TQM

(a) Ethics (b) Trust

(c) Hard work (d) Team work

(xiii) CDSCO is headed by:

(a) DGHS

(b) DCGI

(c) Health Minister State

(d) Health Minister Central

(xiv) 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

(xv) Who is the Drug regulatory authority of India

(a) FDA (b) CDSCO

(c) NRHM (d) NHM

(xvi) The drug development Team comprise of

(a) Discovery and development group

(b) Non-clinical group

(c) Clinical group

(d) All of the above

(xvii) DMAIC stands for:

(a) Design-measure-analysis-improve-control

(b) Develop-measure-analysis-improve-control

(c) Design-manufacture-analysis-improve-control

(d) None of the above

(xviii) Which ICH guidelines explain the process of QRM?

(a) Q9 (b) Q10

(c) Q8 (d) Q11

(xix) ISO 9000 was first published in

(a) 1987 (b) 1986

(c) 1985 (d) 1988

(xx) TQM is

(a) Product oriented

(b) Process oriented

(c) Customer Oriented

(d) Sale oriente

2. Answer any *seven* questions: (7 × 5 = 35)

(a) Write a short note on CDSCO.

(b) Define ToT as per WHO. What are the steps of technology transfer?

(c) What are the key elements of TQM? Explain in details.

(d) Elaborate the role of regulatory affairs department.

(e) What are the problems faced during the commercialization of ToT?

(f) Define QRM. Write the principle and characteristics of QRM.

(g) What do you mean by Six Sigma concept? Explain.

(h) Write a note on ISO 9000.

(i) Explain the objectives and functions of APCTT.

3. Answer any *two* questions: (2 × 10 = 20)

(a) What is pilot plant scale up? Write the reason, objective and general consideration of pilot plat scale up technology.

(b) Define "Technology Transfer"? Elaborate the WHO guidelines for technology transfer.

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