Total No. of printed pages = 3

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

2021

B.Pharm. 7th Semester (Regular) Examination

INDUSTRIAL PHARMACY-II (THEORY)

(New Regulation)

(W.e.f. 2017-2018)

Full Marks – 75 Time – Three hours

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

1. Answer all the questions :

(A) Choose the most appropriate alternative for the following multiple choice questions. (10 × 1 = 10)

(i) 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

(ii) SUPAC guideline deals with

(a) Level of changes

(b) Filing documentation

(c) Recommend chemistry, manufacturing and control tests

(d) All of the above

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

(a) CTD

(b) Technology Transfer report

(c) Technology Transfer dossier

(d) DMF

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(iv) 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

(v) APCTT headquarter is situated at:

(a) Delhi (b) Mumbai

(c) Bangalore (d) Chennai

(vi) ———— filed before conducting the clinical trials

(a) ANDA (b) INDA

(c) NDA (d) None of the above

(vii) 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

(viii) CDSDO is headed by:

(a) DGHS (b) DCGI

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

(ix) 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

(x) Which is NOT a key element of TQM

(a) Ethics (b) Trust

(c) Hardwork (d) Teamwork

(B) Define the following terminologies briefly (5 × 2 =10)

(i) TQM

(ii) GLP

(iii) NABL

(iv) CDSCO

(v) NDA

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

(a) What is bioequivalence studies? Describe in details.

(b) What are the steps of technology transfer? Write the reason for technology transfer.

(c) Explain the objectives and functions of APCTT.

(d) Elaborate the role of regulatory affairs department.

(e) Explain the Non-clinical drug development process.

(f) Write a short note on Quality Risk Management.

(g) What are the key element of TQM? Explain in details.

(h) Write a short note on Six Sigma concept.

(i) Discuss in detail about ISO 9000.

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

(a) What do you mean by the term Technology Transfer"? Discuss detail about WHO guidelines for technology transfer.

(b) What is pilot plant scale up? Discuss the pilot plant scale up consideration for solid dosage form.

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