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BP 702 T

2024

B.Pharm. 7th Semester End-Term Examination

INDUSTRIAL PHARMACY — II

Full Marks – 75 Time – Three hours

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

1. Answer the following (Multiple Choice Questions) : 1×20

(i) In TQM the main emphasis is on

(a) Prevention of errors (b) Detection of errors

(c) Correction of errors (d) None of the above

(ii) GEAC works under

(a) Ministry of Health and Family Welfare

(b) Ministry of Science and Technology

(c) Ministry of Chemicals and Petrochemicals

(d) Ministry of Environment and Forest

(iii) LD 50 stands for

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

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

(iv) Module-2 of CTD is

(a) Administrative prescribing information

(b) Overview and summary of modules 3-5

(c) Quality (pharmaceutical documentation)

(d) Safety toxicology studies

(v) Quality management systems requirements are mentioned in

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

(c) ISO 9000 : 2015 (d) ISO 9011 : 2018

[Turn over

(vi) Which of the following is not a function performed by R & D in the transfer of technology?

(a) Supports technical issue

(b) Directs and trains the procedural trial at RU

(c) Resolves technical problems

(d) Regulatory filing

(vii) INDA filing is done for

(a) Conducting animal studies (b) Conducting human studies

(c) Conducting plant studies (d) None of the above

(viii) Which of the following is not among 5 Cs that are essential for the success of the transfer of technology?

(a) Co-ordination (b) Capacity

(c) Co-operation (d) Chasing

(ix) The use of which drug by pregnant women in 1956 led to phocomelia in newborn babies

(a) Sulphanilamide (b) Penicillin

(c) Thalidomide (d) None of the above

(x) 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

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

(a) FTA (b) HAZOP

(c) HACCP (d) All of the above

(xii) Yellow card scheme was introduced in

(a) 1966 (b) 1964

(c) 1970 (d) 1971

(xiii) The unit from where a designated product, process or method is expected to be transferred is known as

(a) Sending unit (b) Receiving unit

(c) Processing unit (d) None

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

(a) Q9 (b) Q10

(c) Q2 (d) Q1

(xv) The FDA will review and issue an approval, approvable, or non-approvable letter within 180 days of receipt of the application. This period is known as

(a) Filing time frame (b) Patent time frame

(c) Review time frame (d) None of the above

(xvi) APCTT headquarter is situated at

(a) Delhi (b) Mumbai

(c) Bangalore (d) Chennai

(xvii) The batch which have approximately 10% of production-scale batch are known as

(a) Pre-exhibit batch (b) Exhibit batch

(c) Scale-up batch (d) None of the above

(xviii) CDSCO is headed by

(a) DGHS (b) DCGI

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

(xix) In which type of method for technology transfer owner/developer of technology grant permission to another party with full rights and for even

(a) Licensing-in (b) Joint venture

(c) Licensing-out (d) Support contract

(xx) What does SUPAC stand for?

(a) Scale-up and post-approval changes

(b) South-western plant authorities

(c) Scale-up and pre-approval changes

(d) Scale-up and post-accreditation changes

2. Answer any *seven* questions. 7×5

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

(b) Explain organisation and management of transfer of technology.

(c) What is CoPP? What is the process of getting CoPP? 1 + 4

(d) How does regulatory affairs department of the company work as a bridge between the company and the government? Why regulatory affairs department is essential for the company? 2.5 + 2.5

(e) What is Six Sigma concept? Explain its characteristics. 1 + 4

(f) Explain the reasons for occurrence of Out of Specifications (OOS).

(g) Draw the organisation chart of CDSCO. Explain the functions of CDSCO. 2.5 + 2.5

(h) Explain the importance of biostatistics in drug development process.

(i) What is quality risk management (QRM)? Explain QRM process. 1 + 4

3. Answer any *two* questions. 2 × 10

(a) What is pilot-plant? Explain the operations and general considerations for pilot-plant studies. 1 + 4 + 5

(b) What are the general considerations for data submission in FDA? Write in detail the procedure for NDA filing. 5 + 5

(c) How are quality control and quality assurance related to each other? Explain tools to maintain the quality of pharmaceutical products. 3 + 7