Total No. of printed pages = 4

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23/08/22

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

2022

B.Pharm. 6th Semester End-Term Examination

PHARMACEUTICAL QUALITY ASSURANCE (THEORY)

Full Marks – 75 Time – Three hours

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

1. Answer the following (MCQ) : (20 × 1 = 20)

(i) Precision is calculated by

(a) Standard deviation (b) Mean

(c) Mode (d) Median

(ii) The concept covering all the aspects that influence quality of a product is

(a) Quality control (b) Good Laboratory Practice

(c) Quality Assurance (d) All of the above

(iii) The key element of TQM is

(a) Focus on the customer (b) Continuous improvement

(c) Employee involvement (d) All the above

(iv) SOP denotes

(a) Standard Operating Procedures

(b) Standard Operating Principles

(c) Standard of Processes

(d) Standard Operation Procedure

(v) An established documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting it's predetermined specifications and quality attributes is called as

(a) Validation (b) Equipment validation

(c) Cleaning validation (d) Analytical validation

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(vi) In USA, the GLP regulations was incorporated into the national legislation under

(a) Code of pharmaceutical regulations

(b) Code of federal regulations

(c) Code of economic regulations

(d) Code of industry regulations

(vii) Repeatability also called as

(a) Intra assay precision (b) Inter assay precision

(c) Assay precision (d) Intermediate precision

(viii) OECD stands for

(a) Organization for economic cooperation and development

(b) Organization for economic commerce and development

(c) Organization for education cooperation and development

(d) None of the above

(ix) ISO 9000 was issued in which year

(a) 1987 (b) 1997

(c) 1967 (d) 1989

(x) Analytical method validation is mention in ———— guidelines.

(a) EMEA (b) ICH

(c) WHO (d) GMP

(xi) GLP is a type of which system

(a) Quantity system (b) Quality system

(c) Both (a) and (b) (d) None of the above

(xii) NABL stands for

(a) National Accreditation Board for Testing and Calibration Laboratories

(b) National Acceleration Board for Testing and Calibration Laboratories

(c) Numerous Accreditation Board for Typing and Calibration Laboratories

(d) Numerous Accreditation Board for Typing and Medical Laboratories

(xiii) The GLP principles were published in which year?

(a) 1982 (b) 1971

(c) 1981 (d) 1991

(xiv) TQM is used to satisfy which people

(a) Customers (b) Government

(c) National regulatory body (d) ISO standards

(xv) TQM approach originated in which year?

(a) 1950's (b) 1960's

(c) 1970's (d) 1980's

(xvi) The ———— of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found.

(a) Accuracy (b) Precision

(c) Specificity (d) Reproducibility

(xvii) ———— is an internally approved document that describes, in clear and concise wording, the general expectations, intentions, methods and approach to be used during the entire validation effort.

(a) Qualification (b) Validation Master Plan

(c) Calibration Master Plan (d) None of the above

(xviii) TQM stands for

(a) Total quantity management

(b) Total quality management

(c) Total quantity maintenance

(d) Total quality middle management

(xix) The OECD principles of good laboratory practice is incorporated under the membership of

(a) European Directive 87/18/EEC

(b) American Directive 87/18/EEC

(c) European Directive 88/18/EEC

(d) European Directive 87/18/ECE

(xx) Which of the following expression is correct for detection limit?

(a) $DL = 3.3\ S/\sigma$ (b) $DL = 3.3\ \sigma/S$

(c) $DL = 4.3\ \sigma^2/S$ (d) $DL = 3.3\ \sigma^2/S$

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

(a) Give a brief overview of QSEM, with special emphasis on Q-series guidelines.

(b) Give a detailed account on Quality control test for containers, rubber closures and secondary packing material.

(c) Briefly describe about Good Warehousing Practice.

(d) Write in details about Purchase specifications and maintenance of stores for raw materials.

(e) Write in brief about NABL accreditation.

(f) Discuss in detail about the General principles of Analytical Method Validation.

(g) Write short note on : (i) SOP (ii) Quality Audit.

(h) Briefly explain about the Protocol for conduct of a Nonclinical laboratory study.

(i) Write in detail about complaints and evaluation of complaints.

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

(a) Elaborately explain about Good Laboratory Practices.

(b) Write an explanatory note on: Total Quality Management (TQM).

(c) Discuss in brief :

(i) Batch Formula Record

(ii) Validation Master Plan.
