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BP 606T

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

2024

B.Pharm. 6th Semester End-Term Examination

PHARMACEUTICAL QUALITY ASSURANCE – THEORY

New Regulation (w.e.f 2017-18)

Full Marks – 75 Time – Three hours

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

1. Multiple Choice Questions (MCQ) (Answer ALL questions) : (20 × 1 = 20)

(i) _____ is referred to as the "father of Quality Control"

(a) Kaoru Ishikawa (b) W. Edward Deming

(c) Genichi Taguchi (d) None of these

(ii) Guideline for environmental aspects in product standards is in

(a) ISO 9000 (b) ISO 14000

(c) ISO 9001 (d) ISO 26000

(iii) What is the primary goal of Quality Assurance (QA)?

(a) Identify defects after production

(b) Prevent defects before production

(c) Fix defects during production

(d) Ignore defects during production

(iv) Pre market validation is called as

(a) Retrospective (b) Prospective

(c) Design Qualification (d) Concurrent

(v) Which document outlines the detailed steps and controls for manufacturing a pharmaceutical product?

(a) Standard Operating Procedure (SOP)

(b) Certificate of Analysis (COA)

(c) Investigational New Drug Application (INDA)

(d) New Drug Application (NDA)

[Turn over

(vi) Factories Act Came in the year

(a) 1958 (b) 1948

(c) 1968 (d) 1978

(vii) Calibration is necessary for

(a) Qualification (b) Validation

(c) Both (a) and (b) (d) None

(viii) Which of the following is NOT a key element of Quality by Design?

(a) Risk assessment

(b) Design space

(c) Post-marketing surveillance

(d) Control strategy

(ix) Ware housing refers to the process of _____ goods

(a) Holding (b) Storage

(c) Both (a) and (b) (d) None

(x) What is the purpose of a risk assessment in Quality by Design?

(a) To eliminate all risks associated with the manufacturing process

(b) To identify and understand potential risks to product quality

(c) To expedite the drug approval process

(d) To ensure maximum profit margin

(xi) Which regulatory agency is responsible for overseeing pharmaceutical quality in the Australia?

(a) FDA (Food and Drug Administration)

(b) EMA (European Medicines Agency)

(c) WHO (World Health Organization)

(d) TGA (Therapeutic Goods Administration)

(xii) Good documentation is an essential part of

(a) Quality control

(b) Quality assurance

(c) Production

(d) All of the above

(xiii) ICH discusses _____ aspects of production registration

(a) Scientific (b) Technical

(c) Both (a) and (b) (d) None

(xiv) Water attack test is only used for_____ glass containers?

(a) Type I (b) Type II

(c) Type III (d) None

(xv) For accelerated stability condition RH is

(a) 60% (b) 65%

(c) 70% (d) 75%

(xvi) ICH Q9 is for

(a) Safety assessment

(b) Quality risk management

(c) Product development

(d) None

(xvii)The Sub Part B of GLP deals with

(a) General provisions

(b) Organization and personnel

(c) Disqualification of testing facilities

(d) Records and reports

(xviii)_____ provides direction to the entire process of TQM

(a) Trust

(b) Leadership

(c) Communication

(d) Integrity

(xix) One of the important aspects of Equipment validation is

(a) Installation Qualification

(b) Performance Qualification

(c) Process Qualification

(d) Process Validation

(xx) SOP means

(a) Standard of Purpose

(b) Standard Operating Procedure

(c) Single Operating Procedure

(d) Standard Operation Process

2. Long answers (Answer any *two* out of *three*) : (2 × 10 = 20)

(a) What is GMP? Write a note on organization and personnel aspects of GMP.

(b) Write in details about the responsibilities of QA and QC department in pharmaceutical Industry. (10)

(c) What do you mean by caliboration and validation? Write in detail about types of validation. (2+2+6=10)

3. Short answers (Answer *seven* out of *nine*) (7 × 5 = 35)

(a) Write in details about the process of handling of return and recalled goods.

(b) Describe with an overview of elements in QbD.

(c) What is GLP? Explain about the different aspects of GLP.

(d) Write a note on Q series of ICH guidelines.

(e) What are steps involved in ISO 9000 registration process?

(f) Write a note on TQM.

(g) Enumerate the aspects of Good warehousing practices?

(h) Explain the ICH stability testing guidelines.

(i) What is Pharmaceutical documentation? Explain the different parts of SOP.