Total No. of printed pages = 4

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

2020

B.Pharm. 6th Semester End-Term Examination

QUALITY ASSURANCE

(New Regulation)

Full Marks – 75 Time – Three hours

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

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

(i) GMP ensures which of the following parameters

(a) Quality (b) Safety

(c) Efficacy (d) All of the above

(ii) According to WHO QC is a part of ————————

(a) GLP (b) GMP

(c) GCP (d) None of the above

(iii) Which department is responsible for evaluation of Batch records?

(a) QA (b) QC

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

(iv) TQM aims at long term success through

(a) Customer satisfaction (b) Owner satisfaction

(c) Management satisfaction (d) All of the above

(v) ICH Q1 guideline is for ————————

(a) Stability testing (b) Animal testing

(c) ADR (d) None of the above

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(vi) The aim of Pharmaceutical development is to design a ———— product

(a) Optimized (b) Effective

(c) Quality (d) None of the above

(vii) Quality by Design is a concept first outlined by

(a) Joseph M.Juran (b) Robert Nash

(c) Sidney Willing (d) Ishikawa

(viii) In which year ISO was established?

(a) 1926 (b) 1936

(c) 1946 (d) 1956

(ix) NABL is registered under ———— act

(a) Societies

(b) D and C

(c) Environmental protection

(d) None of the above

(x) ISO 9000 deals with the fundamentals of

(a) Risk Assessment

(b) Quality management system

(c) Optimization

(d) None of the above

(xi) In which year Factories act came into existence?

(a) 1958 (b) 1948

(c) 1968 (d) 1978

(xii) Which of the following is important during purchase of raw materials?

(a) Quality (b) Purity

(c) Identity (d) All of the above

(xiii) Light sensitive material should be stored in ———— container

(a) Transparent (b) Amber color

(c) Plastic (d) None of the above

(xiv) Water attack test is used for ———— glass containers

(a) Type I (b) Type II

(c) Type III (d) Type IV

(xv) Headquarter of ISO is situated in ————————

(a) Delhi (b) Geneva

(c) Mexico (d) London

(xvi) ICH Q5 is guideline for ———————— products

(a) Biotechnological

(b) Potent drug

(c) New products development

(d) None of the above

(xvii) ———————— is often referred as the 'Father of Quality Control'

(a) Genichi Taguchi

(b) W. Edwards Deming

(c) Ishikawa

(d) F. Dannison

(xviii) BMR is a ———————— specific document

(a) Product (b) Batch

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

(xix) Validation involves the systematic study of ————————

(a) System (b) Facility

(c) Process (d) All of the above

(xx) In all industries ———————— of SOPs will remain same

(a) Content (b) Structure

(c) Concepts (d) All of the above

2. Answer any SEVEN from the following : (7 × 5 = 35)

(a) Give a clear cut distinction between QA and QC.

(b) Explain the elements of TQM.

(c) What are the responsibilities of QA and QC department in Pharmaceutical industry'?

(d) What are the objectives and benefits of ISO 9000?

(e) What are the benefits of NABL accreditation?

(f) Add a note on personnel responsibilities.

(g) Give the Quality control test for plastic containers.

(h) Write a note on Animal care facilities.

(i) What is the purpose of calibration?

3. Answer any TWO from the following : (2 × 10 = 20)

(a) Explain in detail about ICH Q-series guidelines.

(b) Write the steps required in ISO 9000 registration process.

(c) Discuss the Maintenance and calibration of Equipment.