13/2/23

Total No. of printed pages = 4

MPH 103 T

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

2023

M.Pharm. 1st Semester (Regular) Examination

MODERN PHARMACEUTICS

(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) Type ———— Dissolution Apparatus is used for maintaining Sink Condition

(a) I (b) III

(c) IV (d) V

(ii) Which of the following technique is most suitable for studying drug Crystallinity?

(a) Thermal analysis (b) XRD

(c) Hot stage microscopy (d) Single Crystal X Ray

(iii) Which of the following is called Pre-marketing Validation?

(a) Prospective Validation (b) Retrospective Validation

(c) Concurrent Validation (d) Revalidation

(iv) In Tablet Compression Stress is equal to:

(a) Force/Area (b) Force/Strain

(c) Area/Force (d) None of the above

[Turn over

(v) ———————— is a series of test that measure the performance capability of the equipment

(a) Installation Qualification (b) Design Qualification

(c) Performance Qualification (d) Operation Qualification

(vi) The following equation holds for Force Distribution during compaction

(a) $F_A = F_L + F_D$ (b) $F_A = F_L F_D$

(c) $F_A = F_L / F_D$ (d) None of above

(vii) Solubility of acidic or basic drug must be determine over the pH range of

(a) 2-10 (b) 1-8

(c) 3-12 (d) 1-5

(viii) BET Theory of adsorption is used to determine

(a) Particle Volume (b) Particle Shape

(c) Surface Area (d) Particle size

(ix) The ICH Code Q1B stands for the guideline title

(a) Stability of new drug substance and product

(b) Stability testing of new dosage form

(c) Evaluation of stability data

(d) None of the above

(x) Which of the following dosage form is regarded as thermodynamically stable?

(a) Emulsion (b) Suspension

(c) Microemulsion (d) Multiple emulsion

(xi) The following method of optimization is more suitable for three or more levels

(a) Full Factorial Design (b) Fractional Factorial Design

(c) Star Design (d) Central Composite design

(xii) Which is of the following isn't a mechanism of Tablet Compression

(a) Fragmentation (b) Rearrangement

(c) Chipping (d) Deformation

(xiii) Which of the following technique is not suitable for drug-excipient study?

(a) HPLC (b) DSC

(c) DRS (d) NMR

(xiv) According to BCS classification Class II drugs are having

(a) High Solubility and High Permeability

(b) Low Solubility and High Permeability

(c) High Solubility and Low Permeability

(d) Low Solubility and Low Permeability

(xv) Solubility of acidic or basic drug must be determine over the pH range of

(a) 2-10 (b) 1-8

(c) 3-12 (d) 1-5

(xvi) What is the meaning of "current" according to GMP regulation?

(xvii) ANOVA stands for ——————

(xviii) Define Heckel plot.

(xix) —————— is a common method for statistical optimization.

(xx) What do you mean by IQ facilities?

2. Answer any *seven* from the following: $(7 \times 5 = 35)$

(a) Write the content of Master formula as per WHO.

(b) What are dependent and independent variables in optimization? Give the applications of Quality by Design (QbD) in Pharmaceutical Industries.

(c) Give a brief description of physics of tablet compression.

(d) Differentiate between GMP, QC and QA.

(e) Discuss the factors affecting dissolution.

(f) Write a brief note on the theoretical aspects of SMEDDS.

(g) Describe the applications of factorial designs and contour designs in pharmaceutical formulations.

(h) Differentiate IQ, DQ, OQ and PQ in Pharmaceutical Validation.

(i) Write a brief note on total quality management.

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

(a) (i) Write a brief note of linearity concept of significance. (4)

(ii) Write in detail on various aspects of preformulation studies in dosage form designs and its importance. (6)

(b) (i) Give the advantages of Pharmaceutical validation. Explain in details various Phases of Equipment Validation. (5)

(ii) Explain in details the different types of Process validation. Give the change Control Classifications. (5)

(c) (i) Write in details on various guidelines for Plant Layout and Services as per GMP. (6)

(ii) Mention the objectives of cGMP. (4)