29/3/22

Total No. of printed pages = 4



**MPH 103 T**

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

**2022**

**M. Pharm. 1st Semester End-Term Examination**

**Pharmaceutics**

**MODERN PHARMACEUTICS**

**(New Regulation (w.e.f. 2017 – 18))**

Full Marks – 75 Time – Three hours

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

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

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

(a) Prospective Validation

(b) Retrospective Validation

(c) Concurrent Validation

(d) Revalidation

(ii) In Tablet Compression Stress is equal to:

(a) Force/Area

(b) Force/Strain

(c) Area/Force

(d) None of the above

(iii) _____ 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

(iv) The first mathematical equation that describes drug release from matrix system

(a) Higuchi model

(b) Hixon Crowell model

(c) Korsmeyer Peppas model

(d) Zero Order model

(v) A linear relationship between relative porosity of a powder and the applied pressure is known as

(a) Heckel Plot (b) Force displacement curve

(c) Compaction Profile (d) None of the above

(vi) 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

(vii) _____ is an increase in the mechanical strength of material resulting from Particle/Particle Interactions.

(a) Consolidation (b) Compression

(c) Deformation (d) None of the above

(viii) 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

(ix) BET Theory of adsorption is used to determine

(a) Particle Volume (b) Particle Shape

(c) Surface Area (d) Particle size

(x) 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

(xi) ———— is the increase in mechanical strength of material resulting from particle/particle interactions

(a) Consolidation (b) Compression

(c) Deformation (d) None of above

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

(a) Fragmentation (b) Rearrangement

(c) Chipping (d) Deformation

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

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

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

(xiv) Which of the following theories is not relevant to bonding of particles during tablet compaction

(a) Mechanical Theory

(b) Intermolecular Theory

(c) Liquid surface film theory

(d) BET Theory

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

(a) I (b) III

(c) IV (d) V

(xvi) Ostwald Ripening is observed in ———— type of dosage forms.

(xvii) Angle of repose is determined by the equation ————

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

(xix) ANOVA stands for ————

(xx) Define Heckel plot.

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

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

(b) What is consolidation? Discuss the various consolidation parameters.

(c) Write a brief note of linearity concept of significance.

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

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

(f) Explain what you mean by response surface methods in statistical Optimization.

(g) Differentiate between GMP, QC and QA.

(h) Explain in brief theory of dispersions and Pharmaceutical Dispersions.

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

3. Answer any two out of three: $(2 \times 10 = 20)$

(a) (i) What do you mean by Preformulation study? Give its importance. (3)

(ii) Write in detail on various aspects of preformulation studies in dosage form designs and its importance. (7)

(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. (5)

(ii) Enumerate the ten principles of GMP. (5)