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Total No. of printed pages = 6

MPH 103 T

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

2019

M. Pham. 1st Semester End-Term Examination

MODERN PHARMACEUTICS

(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. Answer the following questions $(20 \times 1 = 20)$

   (i) Formal pre-formulation study should start at the point after ————————, when a decision is made for further development.

   (ii) Microscopic techniques used for measuring particles of size ———————— (Choose the correct option)

   (a) $1-100\mu m$

   (b) $>50\mu m$

   (c) $>1\mu m$

   (d) All of the above

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(iii) DoE was discovered in 1925 by _____

(iv) Instrinsic dissolution rate of can be accomplished best using the _____ of *Wood et.al.*

(v) Brinell test is used to determine (Choose the correct option)

(a) Compressibility and compact ability

(b) Hardness

(c) Wettability

(d) Surface area

(vi) The ICH code Q1B stands for the guideline title (Choose the correct option)

(a) Stability of new drug substances and product

(b) Stability testing for new dosage form

(c) Evaluation of stability data

(d) None of the above

(vii) Which of the following equation is known as Heckel Equation? (Choose the correct option)

(a) $Log\ 1/E = KyP + K_r$

(b) $Log\ E = K_y + K_r$

(c) $Log\ F_t = LogF_m - K1$

(d) None of the above

(viii) Aqueous solubility of every new drug must be determined as a function of pH over the physiological pH range of ————————

(ix) ———————— is called as pre-marketing validation?

(x) Which of the following instrumental method give most complete information about solid state? (Choose the correct option)

(a) Single–crystal X–ray

(b) Dilatometry

(c) Thermal analysis

(d) IR Spectrophotometry

(xi) Ostwald ripening is observed in ————————

(xii) ———————— is an increase in the mechanical strength of material resulting from particle/particle interactions. (Choose the correct option)

(a) Consolidation

(b) Compression

(c) Deformation

(d) None of the above

(xiii) Which section of cGMP under 21CFR 211 refer to the validation of computerized and automated process? (Choose the correct option)

(a) 211.68

(b) 211.84

(c) 211.110

(d) 211.113

(xiv) Select storage condition for accelerated stability study for solid oral dosage form of Zones I/II (Choose the correct option)

(a) 40°C/75%RH

(b) 40°C/60%RH

(c) 50°C/75%RH

(d) 25°C/40%RH

(xv) Operational Qualification is a series of tests that measure the ———— of the equipment.

(xvi) Graphical optimization displays the area of ————in the factor space.

(xvii) Which of the following tablet excipients is known as AcDiSol. (Choose the correct option)

(a) Crospovidone N.F

(b) Croscarmellose N.F

(c) Sodium starch glycolate N.F

(d) None of the above

(xviii) ———— is the first mathematical model that describes drug release from matrix system.

(xix) Passion ratio is related with ————

(xx) Permeation across biological membrane can be studies by (Choose the correct option)

(a) Rotating disk method of *wood et at.*

(b) Crane and Wilson method

(c) Noyes-Nernst dissolution method

(d) All of the above

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

(a) What are the objectives of compatibility studies? Explain drug excipients compatibility testing with a suitable illustration.

(b) Discuss the formulation consideration of large volume parenterals.

(c) Discuss the importance of statistical design in formulation development? Compare the merits and limitation of factorial and central composite design.

(d) What are the factors need to be considered in design of a dissolution test? Write the objectives and method for comparison of dissolution profile.

(e) Discuss the ICH and WHO guidelines for calibration and validation of equipments.

(f) Explain the layout of buildings and services as per cGPM for pharmaceuticals.

(g) Define validation and explain regulatory basis of validation as per cGPM under 21CFR 211.

(h) Explain the different phases of process validation.

(i) Explain compaction profile of tablet machine with proper illustration.

3. Answer the following questions (any two) $(2 \times 10 = 20)$

(a) Explain and classify experimental design. Give a systematic approach for optimization of pharmaceutical formulation considering any one of the experimental design.

(b) Explain physics of tablet compression with relevant mathematical equations involved in different stages of tablet compression. Discuss factors influencing compression force.

(c) Write notes (any two)

(i) Permeation study across biological membrane.

(ii) Total Quality Management.

(iii) Pre-formulation study protocol.
