M 165/015

Enrolment Number										

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M Pharm (Pharmaceutics) Semester Examinations

Modern Pharmaceutics

Course Code: MPH103T

Full Marks – 75 **Time – 3 hours**

The figure in the margin indicates full marks for the questions.

1. Answer the following questions. **20×1=20**

(a) Enlist the contents of Master Formula.

(b) Give the criterias for vendor selection in Pharmaceutical validation.

(c) Explain the method for determination of solubility in preformulation studies.

(d) Explain what you mean by buffer stock in material management.

(e) Explain test of significance in biostatistics.

(f) Explain what you mean by Brittle fracture.

(g) Give the limitations of OVAT system of optimization.

(h) Enlist some instruments used for Drug-excipients interaction studies.

(i) Give a short description on sales forecasting.

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

2. Answer any seven from the following: **7×5=35**

(a) Give the GMP guidelines for Plant layout and stores in Pharmaceutical Manufacturing Industries.

(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) Explain various aspects of stability testing of Pharmaceutical suspensions and emulsions.

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

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

(i) Give the ten principles of GMP

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

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

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

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

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

(iii) (a) Explain in details the objective and functioning of material management systems as per GMP. (6)

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