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MC-MPH-103T

Seat No. _____

M. Pharm (Sem. I) (CBCS) Examination

December – 2017

MPH - 103 T : Modern Pharmaceutics

Time : **3** Hours] [Total Marks : **75**

Instruction : Figures to the right indicates marks

1 Answer the following questions : **10×2=20**

(a) Define validation with its application.

(b) What do you mean by Similarity factors f2 and fl ?

(c) What do you mean by limit of detection and robustness?

(d) What do you mean by Mater Formula Record?

(e) Enlist the role of Implementation of GMP in manufacturing unit.

(f) What do you mean by coding in DOE?

(g) Explain the term: IQ and PQ

(h) Enlist the evaluation tests for identification of Emulsions.

(i) Define RSM, independent variables and dependent variable.

(j) Enlist the preventive measurement which are taken for avoid cross contamination.

2 Answer any **two** out of the following : **2×10=20**

(a) Give a brief idea about production planning and control.

(b) Write a detailed note on Physicochemical parameters affect on Preformulation study.

(c) Write a brief note on 3^2 Factorial Design.

3 Answer any **7** out of the following : **7×5=35**

(a) Discuss the self-inspection and Quality audit proposed by FDA regarding maintenance of pharma. Mfg. unit.

(b) Explain Drug Excipients compatibility study.

(c) Write a note on physiological and formulation consideration, of Parenteral formulations along with its evaluation.

(d) Explain Stability aspects of Emulsion.

(e) Give a brief Introduction on Chi square test, Students T-test and ANOVA test.

(f) Write a short note on compaction and compression along with its effect on various parameters.

(g) Explain in detail about validation of tablet dosage form.

(h) Give prototype sample of site master file and discuss each component of it in detail.

(i) Explain in detail about validation Protocol.