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MD-MQA-104-T Seat No. _____

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

January - 2018

MQA - 104-T : Product Development & Technology Transfer

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

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

(a) What is the full form of CDSCO, SUPAC, BACPAC and SNDA ?

(b) What is post marketing surveillance ?

(c) Enlist the physicochemical properties for Preformulation studies.

(d) What is the layout of pilot plant scale up study ?

(e) What are the evaluation parameter for pharmaceutical packaging material ?

(f) What do You mean by secondary packing materials ?

(g) Define technology transfer.

(h) Enlist the methods to improve solubility of drugs.

(i) Give the name of stability test during product development.

(j) What are the equipment used for the large scale manufacturing of tablet ?

2 Answer the following : (any **two**) **2×10=20**

(a) Discuss the development and informative content for IND and ANDA.

(b) What is co-solvency ? Discuss the use of surfactants and its importance in preformulation studies.

(c) Describe the pharmaceutical packaging materials for medical device and discuss the selection and evaluation parameter of medical device packaging.

3 Answer the following : (any **seven**) **7×5=35**

(a) When, Why and Where technology transfer is needed ?

(b) Discuss the different quality control test for container and closures.

(c) Briefly discuss the product registration guidelines for CDSCO.

(d) Discuss the techniques for the study of crystal properties and polymorphism.

(e) What are the issue facing modern drug packaging system ?

(f) Describe the new era of drug products : Opportunities and challenges.

(g) Discuss the stability testing during product development.

(h) Describe the documentation in technology transfer.

(i) What are the formula, equipment and quality control for parenteral dosage form ?
