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MC-MQA-103-T

Seat No. _____

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

December – 2017

MQA-103T : Quality Control & Quality Assurance

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

Instructions : (1) Figures to the right indicates full marks.

(2) Draw neat and clean diagram as required.

1 Explain the following terms with suitable example : **10×2=20**

(a) Change control

(b) Deviation

(c) IPR

(d) Copyright

(e) GMP

(f) SOP

(g) Quality Audit

(h) GLP

(i) CTD

(j) Packaging.

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

(a) Write an informative note on purchase specifications and maintenance of stores for raw materials.

(b) Enlist and discuss the different part of Schedule M.

(c) What are the basic principles of documentation in pharma industry? Discuss in detail about Master batch record and electronic data handling

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

(a) Write a short note on positive and negative aspects of IPR.

(b) Discuss In-process quality control and finished product quality control for Parental dosage form.

(c) Write an informative note on Three tier documentation.

(d) Write a short note on batch manufacturing record.

(e) What are the scopes of GLP? Briefly discuss about protocol for conduct of non clinical testing.

(f) Write a short note on handling of waste and scrap disposal.

(g) Write an informative note on CTD.

(h) Write a brief note on mix-ups and cross contamination.

(i) Discuss In-process quality control and finished product quality control for surgical products.
