* J B Q - 1 0 1 - T *

JBQ-101-T

Seat No. _____

Master of Pharmacy (Sem. I) Examination

January - 2020

MRA - 101T : Good Regulatory Practices

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

1 Answer the following questions : (Any **Ten**) **10×2=20**

(a) What is the importance of 21 CFR Part 11.
(b) Define : Accuracy, Qualification
(c) Define two aspects of quality.
(d) What is the classification of medical devises as per their risk level according to USFDA.
(e) Give the significance of Six sigma.
(f) Enlist parameters for method validation.
(g) Enlist the regulation requirement for import the medical devices.
(h) Draw the schematic illustration of the concept of GAMP-5.
(i) Enlist the audit tools for GLP.
(j) Write the importance of GDP.
(k) Give importance of VMP.

2 Answer the following questions : (Any **Two**) **2×10=20**

(a) Write a note on TQM.
(b) Explain HVAC in detail.
(c) Describe FDA regulations for 21 CFR Part 210 and 211.

3 Answer the following questions : (Any **Seven**) **7×5=35**

(a) Discuss about GAMP-5.
(b) Write a note on change control.
(c) Explain about OOS.
(d) Describe water system validation.
(e) Write an informative note on GDP.
(f) Discuss in detail about cleaning validation.
(g) Explain validation of steam.
(h) Write a brief note on manufacturing medical device as per cGMP.
(i) Give information on Good Automated Laboratory Practices.
