Roll No. | | | | | | | | | | | | |

Total No. of Pages : 1

Total No. of Questions : 06

M.Pharmacy(Regulatory Affairs) (2017 Batch) (Sem.–2)

REGULATORY ASPECTS OF MEDICAL DEVICES

Subject Code : MRA-203T

Paper ID : [74939]

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

Q1 a. Give risk based classification of medical devices with examples.

b. Explain the product life cycle of medical devices. (7, 8)

Q2 a. What are quality system regulation of medical devices?

b. Explain the adverse event reporting of medical devices. (7, 8)

Q3 a. Give US regulatory approval process of medical devices.

b. What are post marketing surveillance of medical devices? (7, 8)

Q4 a. Give classification and approval process of medical devices for marketing in European Union.

b. What is the clinical evaluation and investigation procedure of medical devices in China?

c. Explain the regulatory registration procedure of IVDs in Japan. (5×3=15)

Q5 Explain the Quality system requirements (21 CFR Part 820) and labeling requirements (21 CFR Part 801) of medical devices in US. (15)

Q6 a. Enumerate the good clinical practice for the clinical investigation of medical devices.

b. Enumerate the validation and verification of medical devices. (7,8)