Roll No. | | | | | | | | | | | | | Total No. of Pages : 01

Total No. of Questions : 06

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

REGULATORY ASPECTS OF MEDICAL DEVICES

Subject Code : MRA-203T

M.Code : 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.**

1. a) Classify Medical Devices. (10)

   b) Discuss IVDs. (5)

2. Explain in detail the validation and verification of Medical devices. (15)

3. Write notes on the following :

   a) Unique device identification as per US FDA. (8)

   b) Pre-marketed approval as per US FDA. (7)

4. Discuss the major highlights for the devices and in vitro diagnostics as per European Union? (15)

5. Discuss in detail the process for clinical investigation and evaluation of medical devices in relation to Asian Continent? (15)

6. Write notes on the following :

   a) Summary Technical Documents. (5)

   b) Good Clinical Practice for Medical devices. (10)

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.