QP CODE: 213333 **Reg. No:……**

Second Semester M. Pharm Degree Regular Examinations November 2024

M.Pharm (Regulatory Affairs)

Paper - III – Regulatory Aspects of Medical Devices (MRA 203T)

(2019 Scheme)

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

- ***Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space***
- ***Answer all parts of a single question together • Leave sufficient space between answers***
- ***Draw table/diagrams/flow charts wherever necessary***

Essays **(3x10=30)**

1. Classify Medical Devices. Explain the Development of Medical device regulations.Add a note on Medical device product life cycle.

2. Explain the quality system requirements as per 21CFR part 820 and labelling requirement 21 CFR part 801

3. Describe the approval process for in-vitro diagnostics in Europe. Add a note on labelling requirements for IVD's

Short Notes **(9x5=45)**

4. CE (Conformite Europeene) certification process

5. IMDRF (International medical devices regulators forum) study groups

6. Validation and verification of medical devices

7. Investigational device exemption

8. Quality system requirements for medical devices in Japan

9. Guidance documents in ASEAN countries

10. Explain in general on Pre-market approval

11. Clinical investigation plan for medical devices

12. ISO standard 14155:2011

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