Printed Pages: 01 **Sub Code: MPM205**

Paper Id.: | 2 | 5 | 0 | 2 | 1 | 2 | **Roll No.** [redacted]

M PHARM
(SEM II) THEORY EXAMINATION 2017-18
MEDICAL DEVICE REGULATIONS

Time: 3 Hours ***Total Marks: 70***

Note: Attempt all Sections.

SECTION A

1. Attempt *all* questions in brief. **2 x 7 = 14**

a) Write difference between medical devices IVDs and pharmaceuticals.
b) What is summary technical document (STED)?
c) Explain in brief about validation of medical devices.
d) What is the meaning of GHTF?
e) Mention adverse event reporting of medical device.
f) Explain in shortpremarketnotification.
g) Write in short about CE certification process.

SECTION B

2. Attempt any *three* parts of the following: **7 x 3 = 21**

a) Explain in detail about IMDRF structure, functions and regulatory guidelines of IMDRF.
b) Discuss Quality system regulations of medical devices: ISO13485
c) Write about medical devices and IVDs as well as regulatory registration procedures for Asian.
d) Write an illustrative note on regulatory approval process for medical devices with reference to European Union.
e) Write a note on good clinical practice for clinical investigation of medical devices.

SECTION C

3. Attempt any *one* part of the following: **7 x 1 = 7**

a) Write about purpose and functions of summary technical documents.
b) Discuss theprinciples of medical devices and IVDs.

4. Attempt any *one* part of the following: **7 x 1 = 7**

a) Write down about clinical investigation plan for medical devices.
b) Explain verification of medical device.

5. Attempt any *one* part of the following: **7 x 1 = 7**

a) Write classification and regulatory approval process for medical devices.
b) Discuss in detail about pre-market approval (PMA) for quality system requirements.

6. Attempt any *one* part of the following: **7 x 1 = 7**

a) Write down about CE certification process.
b) Explain Basics of *in vitro* diagnostics and approval process with reference to European Union.

7. Attempt any *one* part of the following: **7 x 1 = 7**

a) Describe Registration procedures for Medical device regulations in world health organization.
b) Write down about the quality system requirements for India in brief.