

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0823]

**AUGUST 2023
(APRIL 2023 EXAM SESSION)**

Sub. Code: 3007

**M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – REGULATORY ASPECTS OF MEDICAL DEVICES**

Q.P. Code: 263007

Time : Three hours

Answer ALL Questions

Maximum : 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Write a note on IMDRF and explain in detail about the working groups involved in IMDRF.
2. Explain in detail about ISO 14155:2011.

II. Write notes on:

(7 x 5 = 35)

1. Write a note on Risk based Medical Device Classification as per USFDA and CDSCO.
2. Explain in detail about Summary Technical Document.
3. Write in detail about validation and verification of Medical Devices.
4. Write short note on Unique Device Identification (UDI).
5. Write an account on Invitro Diagnostics and its Classification.
6. Write briefly about CE Certification Process in European Union.
7. Write a note on Medical Device Registration Procedure in China.

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[M.PHARM 1223]

**DECEMBER 2023
(OCTOBER 2023 EXAM SESSION)**

Sub. Code: 3007

**M.PHARMACY DEGREE EXAMINATION
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PAPER III – REGULATORY ASPECTS OF MEDICAL DEVICES**

Q.P. Code: 263007

Time: Three hours

Answer ALL Questions

Maximum: 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Write in detail about quality system regulations of medical devices as per ISO 13485.
2. Explain in detail about regulatory approval process for medical device in US.

II. Write notes on:

(7 x 5 = 35)

1. Write in Detail about Clinical Evaluation of Medical Devices.
2. Write a note on Classification rules of IVD's as per EU regulations.
3. Write in detail about IMDRF study groups.
4. Write short notes on medical device registration procedure in Japan
5. Write in brief about labeling requirements as per 21 CFR part 801.
6. Write a note on Active Implantable medical device.
7. Explain in detail about Pre-Market Approval process.

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[M.PHARM 0524]

**MAY 2024
(APRIL 2024 EXAM SESSION)**

Sub. Code: 3007

**M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – REGULATORY ASPECTS OF MEDICAL DEVICES**

Q.P. Code: 263007

Time: Three hours

Answer ALL Questions

Maximum: 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Write the classification and essential principles of medical devices and in vitro diagnostics (IVDs).
2. Describe the approval process for vitro diagnostics in the US. Add a note on labelling requirements for Medical Devices in the US.

II. Write notes on:

(7 x 5 = 35)

1. The product life cycle of medical devices.
2. Validation of medical devices.
3. Clinical investigation plan for medical devices.
4. Pre-market approval (PMA).
5. Active Implantable medical device directives.
6. The IVDs approval process in Japan.
7. IMDRF guidance document given by the study group.

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[M.PHARM 1124]

NOVEMBER 2024

Sub. Code: 3007

**M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – REGULATORY ASPECTS OF MEDICAL DEVICES**

Q.P. Code: 263007

Time: Three hours

Answer ALL Questions

Maximum: 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Define and classify medical devices. Explain the organizational structure, purpose and function and regulatory guidelines of the International Medical Device Regulators Forum (IMDRF).
2. Explain the quality system regulations of medical devices according to ISO 13485.

II. Write notes on:

(7 x 5 = 35)

1. Explain the salient features of summary technical documentation (STED) format.
2. Explain the validation of a medical device.
3. What are in vitro diagnostics? Classify them with an example.
4. Write a note on premarket notification of medical devices (510K).
5. Describe the CE certification process in the EU.
6. Regulatory Registration Procedure for Medical Devices in Singapore.
7. Write the steps involved in the clinical evaluation of medical devices in China.

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 1025]

OCTOBER 2025

Sub. Code: 3007

**M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – REGULATORY ASPECTS OF MEDICAL DEVICES**

Q.P. Code: 263007

Time: Three hours

Answer ALL Questions

Maximum: 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Define medical device. Explain about the essential principles of medical device and provide a detailed view on how medical devices are different from that of pharmaceuticals. Brief about product life cycle of medical device.
2. Explain the quality risk management of medical device as per ISO14971.

II. Write notes on:

(7 x 5 = 35)

1. Explain about the organization structure, purpose and functions of the GHTF.
2. Brief on ISO:14155:2011.
3. Explain in detail about the premarket notification of medical device in U.S.
4. Brief on quality system regulation of medical device.
5. Provide an overview on the regulatory approval process for medical devices in EU.
6. Write the steps involved in clinical evaluation of medical devices in ASEAN countries.
7. Provide a detailed overview on the post marketing surveillance of medical devices in US.
