



School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-14th (2022-2024)

Second Year, Term 4 End Term Examination, September 2023

PHRM-744 Promotion of Medical Devices in Hospitals

Time - 3 Hour

Maximum Marks: 50 (Minimum Marks: 20)

Instructions to students:

- This question paper contains 2 printed pages.
- Don't write anything on the Question Paper except your Enrolment No.

Part A

(Maximum Marks: 5)

Q1. Answer the following questions by choosing the most correct option.

(1 x 5 = 5)

- (i).are defined as medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers
 - a) Refractory Pump
 - b) Refractory Apparatus
 - c) Medical equipment
 - d) None of the above
- (ii). One of the statement about the marketing features of Urinary catheter is not correct. Identify the incorrect option
 - a) Designed for short term bladder catheterization.
 - b) Made from medical grade thermo-sensitive PVC material.
 - c) Irritant to delicate mucous membranes of urethra.
 - d) Perfectly finished closed distal end for smooth & painless insertion.
- (iii). The license for manufacturing a Class A or B device is issued by the....., while the licensing to manufacture a Class C or D device is issued by the
 - a) State Licensing Authority, Central Licensing Authority.
 - b) Central Licensing Authority, State Licensing Authority,
 - c) State Licensing Authority
 - d) Central Licensing Authority
- (iv). The is the outcome of the bidding process; it is the document that will legally bind the purchaser and supplier to an agreed-upon set of product specifications, delivery requirements, performance and payment obligations of both parties, and legal recourse in the case of non-compliance on either side.
 - a) Arbitration
 - b) Embodiment
 - c) License
 - d) Contract
- (v). Preferred needle gauge for an intradermal injection ranges from 25g to 30g as the needle width is small 0.5mm to 0.3mm and a length of.....
 - a) 8mm to 13mm
 - b) 80 mm to 130 mm
 - c) 60 mm to 120 mm
 - d) 40 mm to 110 mm

Part B

(Maximum Marks: 15)

Answer the following:

(3 x 5 = 15)

- Q2. Define Medical Device as per Section 201(h) of the Food, Drug, and Cosmetic Act. Elaborate the definition taking into account the Diagnosis component citing suitable example.
- Q3. You are working as marketing manager of Romsons Medical Devices. Write the marketing communication for N95 PM 0.3 Mask (GS-9038)
- Q4. Elaborate on the Legal and Regulatory framework for medical devices in India.

Part C

(Maximum Marks: 30)

Answer the following, in detail:

(3 x 10 = 30)

- Q5. Elaborate on the classification of medical devices as per the Medical Device Rules, 2017 of GOI. Cite relevant examples in support of your answer
- Q6. A Healthcare organization wishes to venture in business of Medical devices at national and International Level. If you are appointed as consultant to the organization, What are the inputs you would provide in context to the Indian and the Global Medical Device market for successful business operations of the Organization.
- Q7. AIIMS , New Delhi wish to procure cardiac stents for the Cardiac Surgery department for catering to the needs of the patient undergoing angioplasty. You are working as Procurement Manger in AIIMS, New Delhi. Enlist the steps which you will undertake for procuring a good quality cardiac stent for AIIMS New Delhi.