23124 3 Hours / 80 Marks



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Seat No.						

Instructions -

- (1) All Questions are Compulsory.
- (2) Answer each next main Question on a new page.
- (3) Illustrate your answers with neat sketches wherever necessary.
- (4) Figures to the right indicate full marks.
- (5) Assume suitable data, if necessary.
- (6) Mobile Phone, Pager and any other Electronic Communication devices are not permissible in Examination Hall.
- (7) Answer as per latest amendments.
- (8) In case student has attempted sub-questions of question no. 3 more than once, only first attempt should be considered for assessment.

Marks

1. Attempt any SIX of the following:

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- a) Discuss the qualification and Duties of Drug Inspector.
- b) Discuss the constitution and function of PCI.
- c) What is clinical trial and explain various phases of clinical trail.
- d) Discuss the various functions of CDL as per Drug and Cosmetic Act 1940.
- e) What is the role of pharmacist in relation to his job as per code of ethics.
- f) Give constitution of DTAB.
- g) Discuss the objective DPCO and the Retail Price of Drug is calculated.

2. Attempt any TEN of the following:

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- a) Define Magic remedies and give exempted advertised under DMR Act. 1954. (any four)
- b) Explain the BCS System of classification.
- c) Give general principles of law.
- d) What are the powers of Drug Inspector as per D&C Act, 1940.
- e) Discuss certain operations controlled by Central Govt. under NDPS Act. 1985
- f) Discuss the qualification of Government Analyst.
- g) Discuss documentation, licenses and renewal procedure in Hospital pharmacy.
- h) Define 'Misbranded drug' as per D & C Act, 1940.
- i) Discuss the rules prescribed by the State Government in relation to possession and possession for sale of poison.
- j) What are the functions of the National Council for Clinical Establishment.
- k) Give bonafide reasons for termination of pregnancy under M.T.P., 1971.

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3. Attempt ALL of the following: a) FSSAI stands for ----b) The HQ of CDSCO is located at -----Mumbai ii) Delhi iii) Chennai iv) Kolkata How often we donate blood. After 24 hours ii) After 3 hours iii) After 3 months iv) After 6 months ----- is celebrated as World Consumer Day. 10 April ii) 15 March iii) 28 Feb iv) 1 Jan e) The full form of IAEC is -----Institutional Animal Ethics Committee ii) Institutional Animal Ethics Corporation iiii) Institutional Animal Education Committee iv) None of above f) Give a function of CPCSEA. g) Medical Device Class III is stands for -----h) What does schedule 'S' prescribes under D & C Act, 1940. i) MTP Act was passed in year. The provision of DPCO are implemented and enforced by -----i) i) DPEA ii) NPPA iii) MAPE iv) None of above Give full form NLEM Give one function of National Institute of Disaster Management. Give functions of DTAB. Pharmacist is liaison between ----- & -----n) Define 'Bioethics'. For glass bottle and broken glass articles which bag is used as per biomedical Waste Management Act. State the long form of ICMR. q) Enlist the principles of bioethics. r) Indian Veterinary Research Institute is situated at ----s)

What is Good Regulatory Practices?

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