

## P38/HSC244/EE/20160520

**Time : 3 Hours**

**Marks : 80**

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**Instruction :**

1. All Questions are Compulsory.
  2. Each Sub-question carry 5 marks.
  3. Each Sub-question should be answered between 75 to 100 words. Write every questions answer on separate page.
  4. Question paper of 80 Marks, it will be converted in to your programme structure marks.
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1. Solve any **four** sub-questions.
  - a) Discuss GMP guidelines for premises and materials. 5
  - b) What is need of prevention of Food Adulteration Act, 1954 and explain about central committee for food standards. 5
  - c) Enlist Ex-officio members of Drug Technical Advisory Board. 5
  - d) Explain Adulterated drug and spurious drugs with respect to Drug and Cosmetic Act 1940. 5
  - e) Which details should be filled in 'Master Formula Record' and 'Packaging Records' as per GMP guidelines. 5
  
2. Solve any **four** sub-questions.
  - a) Discuss powers of central government to take measure to protect and improve environment. 5
  - b) What are the criterias for appointment of 'Inspector' with respect of Drug and Cosmetic Act 1940? 5
  - c) Explain in detail the procedure of sending food sample for analysis. 5
  - d) Write short note on documentation and records as per GMP guidelines. 5
  - e) Discuss requirements of garments, changing procedure in sterile manufacturing area. 5

3. Solve any **four** sub-questions.
- a) Explain requirements for manufacturing of oral dosage form with respect to schedule M. 5
  - b) What are the qualification criteria and duties of Public Analyst. 5
  - c) What are the conditions for prohibition of import of certain drugs and cosmetics. 5
  - d) Discuss the requirements of quality control system and quality audits as per GMP guidelines. 5
  - e) What are requirement of warehousing area and ancillary area? 5
4. Solve any **four** sub-questions.
- a) Explain in detail about Environment Protection Act 1986. 5
  - b) Which classes of drugs are included in second schedule of D and C Act 1940. 5
  - c) Discuss about central drug laboratory. 5
  - d) Write short note on Schedule M. 5
  - e) Explain the duties of Food Inspector. 5

