

P48/HSC265/EE/20160518

Time : 3 Hours

Marks : 80

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) Explain the source of microbial source contamination in pharmaceutical preparation. 5
 - b) What is API and Dosage form and why dosage form is needed. 5
 - c) Explain following IPQC test for tablet
 - i) Hardness
 - ii) Friability. 5
 - d) Write down the process flow sheet for Capsule manufacturing. 5
 - e) What is tablet Coating and explain the equipment used for it. 5

2. Solve any **four** sub-questions.
 - a) What is Plasma Drug Concentration - Time Profile and explain following
 - i) Minimum Effective Concentration (MEC)
 - ii) Maximum Safe Concentration (MSC)
 - iii) Duration of action. 5
 - b) What is meant by liquid preparation give its advantages and disadvantages classification and manufacturing process flow sheet. 5
 - c) Explain different excipient used in tablet manufacturing and its importance. 5
 - d) Explain process flow sheet for topical preparations and note on its manufacturing area. 5
 - e) Write down different types of Tablet. 5

3. Solve any **four** sub-questions.
- a) What is capsule give its advantages and disadvantages and its types. 5
 - b) Explain Renal and non renal route of excretion of drug. 5
 - c) Write note on primary packaging material. 5
 - d) What is microbiology and explain characteristic of microorganisms and enlist the types of microorganisms. 5
 - e) What is Dry Granulation and give its Advantages and Disadvantages. 5
4. Solve any **four** sub-questions.
- a) Define :
 - i) Expiry date
 - ii) Shelf life
 - iii) Stability test
 - iv) Manufacturing date
 - v) API 5
 - b) Write down process flow sheet for manufacturing of injectables. 5
 - c) Write down IPQC test for granules. 5
 - d) Explain the factor affecting the Drug Stability. 5
 - e) Write down excipient used in sterile products and its important. 5

