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Roll No .....

PY-803 (GS)

B.Pharmacy VIII Semester Examination, June 2020

Grading System (GS)

Pharmaceutical Analysis - III

Time : Three Hours

Maximum Marks : 70

Note : i) Attempt any five questions.
ii) All questions carry equal marks.

1. Enumerate the steps for development of UV-visible spectrophotometry method for single and two component system.

2. Describe the validation parameters of analytical method with reference to pharmacopoeial requirements.

3. Explain the design and working of type 1 and type 2 dissolution test apparatus? Give the significance of dissolution test of pharmaceutical formulation.

4. Explain in details with suitable examples various validation parameters for analytical method development as per ICH guidelines.

5. Write notes on any two:
   a) Residual solvents
   b) UV spectrophotometer validation
   c) Derivative spectroscopy

6. Explain the limit of quantification of following with respect to Indian pharmacopoeia.
   a) Weight variation
   b) Friability
   c) Disintegration

7. Write exhaustive notes on:
   a) Standard operating procedure
   b) Significance of drug analysis in Body fluids

   OR

   How are waters classified as per Indian pharmacopoeia? What is the role of pH and conductivity in determination of water purity?

8. Write short note on Any Two of the following.
   a) Good laboratory practices
   b) ICH guidelines for residual solvents in drug substances and drug products
   c) Drug analysis in biological fluids

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