Roll No .....

PY - 803

B.Pharmacy VIII Semester

Examination, June 2016

Pharmaceutical Analysis - III

Time : Three Hours

Maximum Marks : 70

Note: i) Answer five questions. In each question part A, B, C is compulsory and D part has internal choice.
ii) All parts of each questions are to be attempted at one place.
iii) All questions carry equal marks, out of which part A and B (Max.50 words) carry 2 marks, part C (Max.100 words) carry 3 marks, part D (Max.400 words) carry 7 marks.
iv) Except numericals, Derivation, Design and Drawing etc.

1. a) What are different steps in an analytical method development?
   b) How analytical method development differs in bulk drugs and dosage form?
   c) Discuss principle of Derivative spectrophotometry.
   d) Outline different condition for stability indicating assay procedure.

   OR

   How analytical method development for blood can be done by HPLC?

2. a) What is validation of analytical method?
   b) Why analytical instruments are validated?
   c) Give method for calibration of UV-visible spectrophotometer as per I.P.

   d) Discuss different parameters used for validation of an analytical method.

   OR

   Outline different steps for validation of HPLC instrument.

3. a) What is the importance of water analysis?
   b) What is impurity profiling?
   c) What is residual solvent? How it is determined?
   d) How water purification system is validated?

   OR

   Explain method for moisture content analysis in drug and dosage forms.

4. a) Explain the procedure for determination of total organic carbon.
   b) What is conductivity test? How it is performed?
   c) Why content uniformity test is performed?
   d) Outline ICH guidelines for impurities in drug products.

   OR

   Outline the assay of paracetamol as per I.P and validation of the method.

5. a) What are good laboratory practices?
   b) Outline the procedure for development of analytical method in combination drug product.
   c) What are OECD guideline for animal testing?
   d) Discuss various phases of clinical trial.

   OR

   What is standard operating procedure? Write on SOP for HPLC.

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