



- Notes :
1. All questions carry equal marks.
  2. Diagrams and Chemical equation should be given wherever necessary.
  3. Illustrate your answers wherever necessary with the help of neat sketches.
  4. All questions are compulsory.

1. Solve **any ten**. **2x10**  
**=20**
  - i) Define optimization.
  - ii) Mention the objectives of cGMP.
  - iii) Define Heckal Plot.
  - iv) Define response surface method.
  - v) Differentiate between validation & calibration.
  - vi) Name various methods of Drug Excipients interaction studies.
  - vii) Define ANOVA Test.
  - viii) Give the full form of IQ, DQ, OQ & PQ.
  - ix) What is the role of friction during tablet punching.
  - x) What does SMEDDS stand for? What is its purpose.
  - xi) What is Total Quality management.
2. Solve the following **any five**. **5x7=**  
**35**
  - i) Write a note on ANOVA.
  - ii) Describe the total quality management.
  - iii) Discuss the preparation & evaluation of SMEDDS.
  - iv) Discuss F1 & F2 factors & calculation with example.
  - v) Discuss the solubility enhancement techniques.
  - vi) Write a note on Inventory Management and production control management.
  - vii) Explain the various optimization techniques in formulation processing with suitable example.
3. Solve the following **any two**. **10x2**  
**=20**
  - i) List out the method used for determination of drug excipient interaction and discuss methods in detail with example.
  - ii) Discuss the ICH guideline for calibration and validation of equipment with example.
  - iii) Write the Heckel equation & draw the Heckel plot for determination of porosity compression of tablet.

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