

Please check whether you have got the right question paper.

- N.B: 1. All questions are compulsory.
2. Draw neat labeled diagram wherever necessary.

- Q.1**
- a) State release rate equation for elementary osmotically controlled drug release system. **02**
 - b) Name the biological indicator, one each, which is recommended for validation of steam sterilization and dry heat sterilization **02**
 - c) Explain briefly 2 important advantages of process validation **02**
 - d) Write briefly on quality control standards of 'identity' **02**
 - e) Explain the terms 'coacervation' and 'phase separation' in context of microencapsulation **02**
 - f) Name two polymers which can be used to provide 'pH based' colon targeted systems. **01**
 - g) Explain importance of vendor audit with reference to raw material control. **02**
 - h) What are A, B and C in ABC concept in inventory management. **02**
- Q.2**
- a) What are microcapsules? Discuss various applications of microencapsulation. **04**
- OR**
- With the help of a diagram, discuss spray drying in microencapsulation.
- b) Draw a neat labeled scheme for manufacturing of oral liquids. **04**
 - c) With reference to schedule M, discuss dust collection and cross contamination in manufacturing facility. **03**
- Q.3**
- a) With the help of a neat labeled diagram, describe components of a typical transdermal drug delivery system. **04**
 - b) Explain the term 'F₀'. what is importance and application of F₀? **04**
 - c) Describe different parts of a good document. **03**
- Q.4**
- a) Discuss importance and salient features of IPQC test. List IPQC tests for tablets. **04**
 - b) Give brief description of the following systems **04**
 - i) Liposomes
 - ii) Microemulsion
 - ii) Pellets
 - iii) Microspheres
- OR**
- b) Discuss buccal adhesive systems in drug delivery
 - c) Discuss briefly site selection, requirements for non-sterile products manufacturing facility. **03**

- Q.5**
- a) Discuss briefly factors affecting mucoadhesion. **04**
 - b) Write one specimen document/protocol for microbiological environmental control of Room no 10 to be used in preparation of oral paracetamol suspension. **04**
 - c) With suitable examples of coating materials, describe steps in microencapsulation of a volatile liquid. **03**
- Q.6**
- a) State the limitations of elementary osmotic pump. Draw a labeled diagram for push pull osmotic system and explain its working. **04**
 - b) Prepare SOP for calibration of dissolution testing apparatus IP type I. **04**
- OR**
- Discuss scale up considerations for powder-powder mixing step in direct compression of tablets.
- c) Discuss 'time' based approach in colon specific drug delivery. **03**
-