

Q.P. Code :0000439

[Time: Two Hours]

[Marks:40]

Please check whether you have got the right question paper.

- N.B:**
- 1. Question number 01 is compulsory.**
 - 2. Answer any three questions from the remaining five questions.**
 - 3. Figures to the right indicate full marks.**
 - 4. Draw a neat labelled diagram wherever necessary.**

- Q.1. Answer any two questions from the following -
- Describe in detail SOP of an autoclave. **05**
 - Give a diagram of a layout for a capsule manufacturing unit. **05**
 - Discuss in brief Raw Material Control. **05**
- Q.2. Discuss in detail importance of pilot scale up studies and describe the considerations in scale up of coated tablets. **10**
- Q.3. a. Define validation. Discuss types of validation. **05**
b. Discuss validation of a Rapid Mixer Granulator. **05**
- Q.4. a. Write a Batch Manufacturing Record of liquid oral preparation. **05**
b. Write the functions of Quality Assurance Cell. **05**
- Q.5. a. Discuss the criteria for vendor selection and importance of vendor audit. **05**
b. Discuss the IPQC testing for an oral suspension. **05**
- Q.6. Write short notes on any two. **10**
- IQ-OQ-PQ
 - QC Charts.
 - Labelling requirements.