First Year M. Pharm Degree Examination - June-2019

[Time: 3 Hours]

Preformulation and Production Management

(Revised Scheme 4)

Q.P. CODE: 9337

Your answers should be specific to the questions asked. Draw neat, labeled diagrams wherever necessary. Answer any ten questions.

LONG ESSAY (Answer any TEN)

- 1. Explain the various parameters considered for physicochemical properties of new liquid drug molecule.
- 2. Enumerate different types of design of experiments and explain any two.
- 3. Define and explain various forces involved in compaction of powders.
- 4. Explain stability testing procedure for a new drug substance.
- 5. Explain ISO 9000 series for quality system.
- 6. Explain modern inventory management system and different methods for evaluation of inventory management system.
- 7. Discuss in detail different about types of material handling system.
- 8. Explain the procedure for filling a product patent in India.
- 9. Discuss the pilot plant procedure adapted for parenterals.
- 10. Explain the safety measures to be undertaken to avoid (a) Fire accidents in pharma industry (b) While cleaning and operating the tablet compression machine.
- 11. Explain about regulatory requirements in TGA and ANVISA.
- 12. Write about Process automation technology in Pharmaceutical manufacturing.

10 X 10 = 100 Marks

[Max. Marks: 100]