

Sl.No: M21590

Course Code: 2910315

**VINAYAKA MISSION'S RESEARCH FOUNDATIONS, SALEM**  
**(Deemed to be University)**

**B.PHARM. DEGREE EXAMINATION – July 2019**  
**Third Year**

**PHARMACEUTICAL QUALITY ASSURANCE**

Time : Three hours

Maximum: 70 marks

I. Write essays on any **TWO** questions: (2 x 15 = 30)

1. Explain the salient features of Good laboratory Practices followed in Pharmaceutical industries.
2. Enumerate various parameters employed in Analytical method validation.
3. Give an account of ISO 9000.

II. Write short essays on any **SIX** questions: (6 x 5 = 30)

4. Describe the basic concept of the TQM.
5. Explain about quality by design.
6. Write the functions of CDSCO as a regulatory body in India.
7. Write a note on NABL certification.
8. What is good warehousing practice?
9. Brief about Hydrolytic resistance test to classify the glass containers.
10. What is six Sigma concepts?
11. Write a note on Standard Operating procedure.

III. Write short notes on any **FIVE** questions: (5 x 2 = 10)

12. Define validation.
13. Applications of computers in QC and QA laboratory.
14. What is calibration?
15. Expand IND, NDA, ANDA and DMF as per US-FDA regulatory guidelines.
16. What is the role of ICH –Q9 guideline?
17. What are the particulars of distribution records?

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