

BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE, INDIA
PhD Entrance Test – 2020
SECTION-II: Quality Assurance Techniques - 50 Marks

Section II	
1	Study of concepts of cGMP covering the following aspects: <ol style="list-style-type: none"> 1. Personnel 2. Building and facilities 3. Equipment 4. Quality Management 5. Post Operational Activities 6. Inspection 7. Manufacturing Operations and Control 8. Sterile Pharmaceutical Activities
2	Pharmaceutical Validation covering the following aspects: <ol style="list-style-type: none"> 1. Introduction to Pharmaceutical Validation. 2. Master Plans 3. Validation of Process 4. Validation of Equipment and Facilities 5. Analytical Method Validation 6. Process validation and Quality assurance
3	Quality Planning and Analysis covering the following aspects: <ol style="list-style-type: none"> 1. Basic concepts of Quality 2. Quality Control 3. Quality Assurance 4. Developing quality culture 5. Quality in Manufacturing 6. Inspection test and measurement 7. Statistical Process Control

References

1. Good Manufacturing Practices by S.H. Wills and J.R. Stoker, Marcker and Dekker incorporations.
2. Good Manufacturing Practices for Pharmaceuticals (6th Edn.) by Joseph D. Nally, Informa Healthcare Publication.
3. Selected International, GMP guidelines of various countries like UK, USA, Australia, South Africa. WHO. India. & ICH guide lines.
4. Pharmaceutical process validation by Robert Nash and A.H. Wachter, Marcel and Dekker Inc. Vol. 129.
5. Validation of pharmaceutical process (sterile products) by F.J. Carleton and J.P. Agalloco Marcel and Dekker Inc.
6. Quality planning and analysis. By J.M. Juran and F.M. Gryna Tata McGraw Hill India. 5th Edition.
7. Improving quality through planned experimentation By Moen.Tata McGraw Hill India.
8. Statistical Process Control by Grant. Tata McGraw Hill India.
9. Pharmaceutical statistics by S. Bolton,; Marcel Dekker Inc.
10. Applied statistics in health care by Rao NSN, Murthy NS. Jaypee Brothers Medical Publishers. New Delhi.
11. Juran's quality handbook; Juran J.M. and Godfrey A.B. McGraw Hill.
12. Pharmaceutical Quality Assurance by M.A. Potdar Nirali Prakashan, Pune.

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