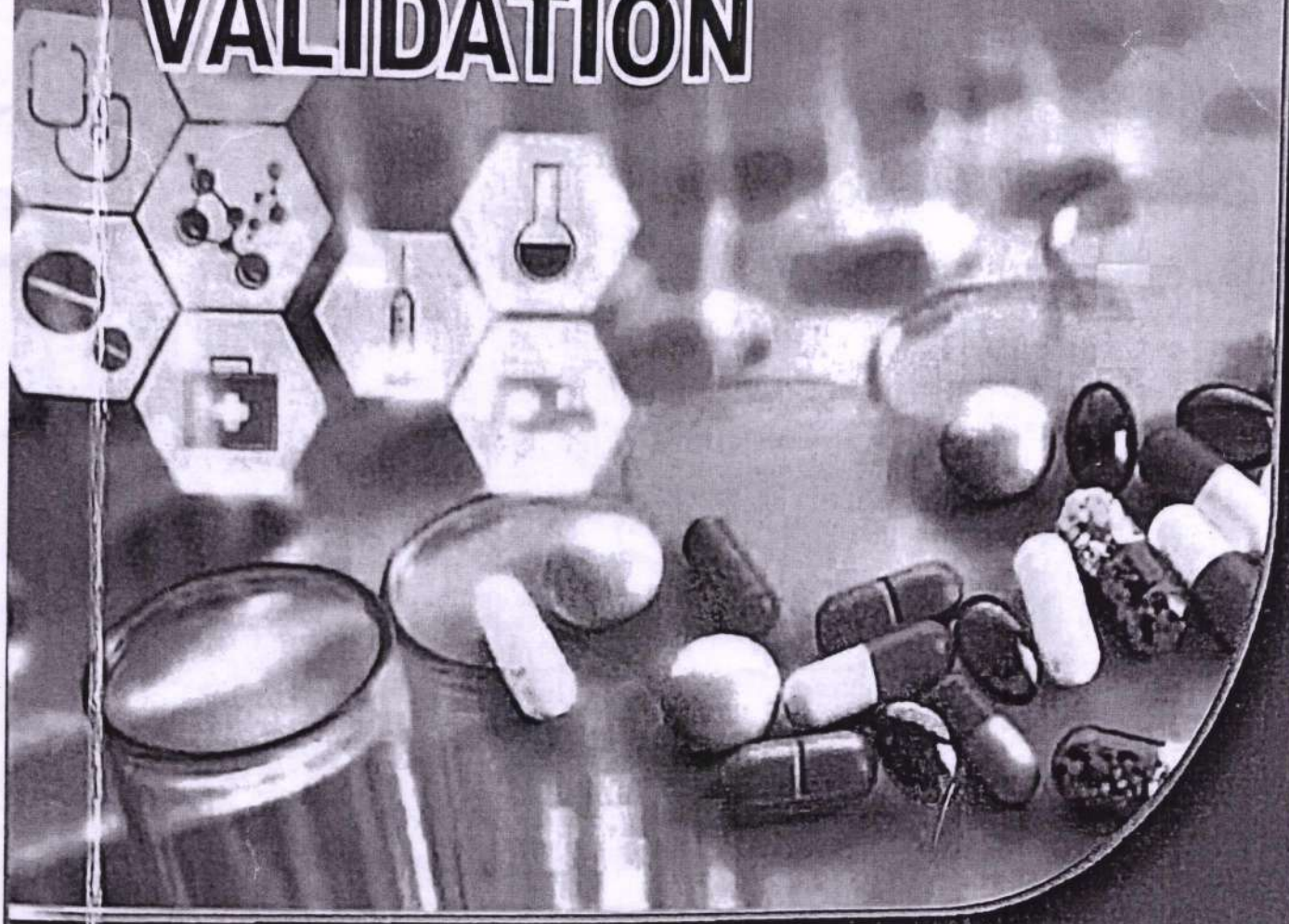
TEXTBOOK OF PHARMACEUTICAL VALIDATION



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PREFACE

The authors take a pragmatic approach and present a comprehensive interpretation of the rules that are currently in place (GMP, ICH), in addition to a discussion of the relevant calculations, parameters, and testing. Therefore, readers will be able to validate the analysis of pharmaceutical compounds using this book, all while adhering to the regulations and meeting the demands of the industry for robustness and cost effectiveness.

After providing an overview of the fundamental parameters and tests used in pharmaceutical validation, such as specificity, linearity, range, precision, accuracy, detection, and quantitation limits, the text then shifts its emphasis to a life-cycle approach to validation and the incorporation of validation into the overall analytical quality assurance system.

Analytical chemists, the pharmaceutical business, pharmacologists, quality assurance officials, and public authorities will find this reference extremely helpful due to the author's first-hand experience of the sector as well as the governing organizations.

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PHARMACEUTICAL VALIDATION

THEORY

1. Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process, and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of analytical Instruments and Laboratory equipment.
2. Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers, and burette.
3. Validation of Utility systems: Pharmaceutical Water System &pure steam, HVAC system, Compressed air, and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation, and Validation of analytical methods used in cleaning.

Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

4. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.
5. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP),Intellectual Property Rights (IPR); Economic importance, a mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting the choice of IP protection; Penalties for violation; Role of IP in the pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types of patent applications: Provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP, and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

AUTHORS BIOGRAPHY

Dr. Raj Kumar Bolledula is an accomplished researcher and eminent teacher in Pharmaceutical Sciences. He is currently working as Professor at Moonray Institute of Pharmaceutical sciences, Raikal, Shadnagar, Telangana. He has completed M.Pharmacy and Ph.D. from Jawaharlal Nehru Technological University Hyderabad, Hyderabad, Telangana. He has 13years of teaching experience. He has more than 30 publications in reputed journals, one patent, an Editorial board member in national and International journals, and a reviewer for international journals. He has guided 25 M.Pharm students. He has attended many symposiums, conferences, and workshops at the national and International levels. He is a Life Member of the Association of Pharmaceutical Teachers of India (APTI) & Indian pharmacy graduate association (IPGA).

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