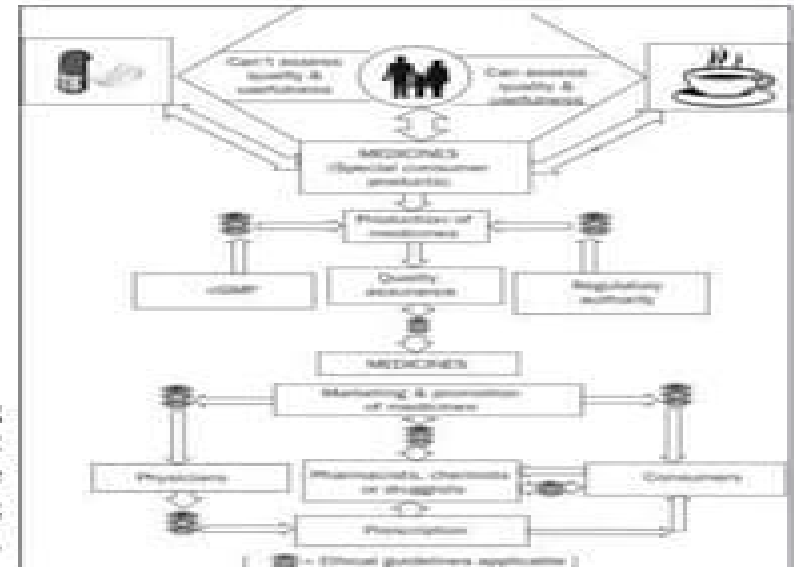


# Current Good Manufacturing Practices (cGMP) and Clean In Place (CIP)

RITHIKA. R. S | II M.Sc. Bioinformatics | Sri Krishna Arts and Science College.

CGMP refers to the *Current Good Manufacturing Practice* regulations enforced by the FDA. CGMPs provide for systems that assure proper *design, monitoring, and control of manufacturing processes and facilities.*

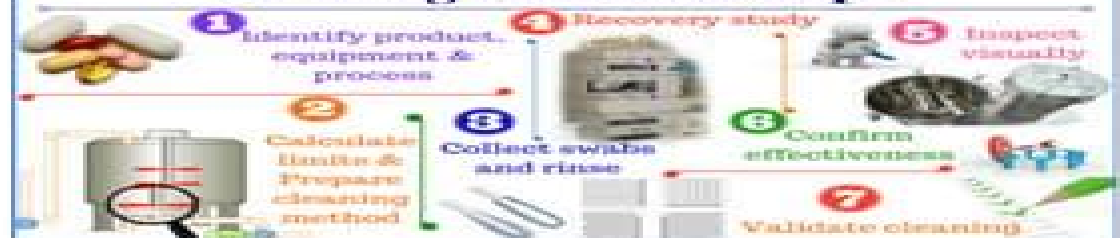
## PRINCIPLES OF GOOD MANUFACTURING PRACTICE (GMP)



Clean-in-place (CIP) is a method of cleaning pharmaceutical manufacturing equipment without the need to disassemble it. The equipment is cleaned using a series of cleaning solutions that are pumped through the system, and then flushed out with water.



## Cleaning Validation Steps



Step	Operation	Cleaning Agent	Temp (°C)	Time (Min.)	Usage
1	Pre-rinse	Water	20-30	2-5	To drain
2	Alkali clean	2% Caustic	70-90	5-30	Recirculated
3	Inter-rinse	Water	20-30	1-5	To drain
4	Acid clean	1% Phosphoric	50-70	3-15	Recirculated
5	Inter-rinse	Water	20-30	4-10	To drain
6	Sterilant	Peracetic Acid	20-30	3-15	Recirculated
7	Final rinse	Water	20-30	4-10	To drain

# Current Good Manufacturing Practices Manual

**SA Dillow**



## **Current Good Manufacturing Practices Manual:**

Good Manufacturing Practices for Pharmaceuticals D. Nally Joseph, 2000-10-12 Highlighting key issues and differences among GMPs of Europe Canada and the WHO this reference examines US law and governmental policy affecting domestic and multinational pharmaceutical manufacturing The book recommend pragmatic ways to interpret and comply with FDA CGMP regulation and related criteria They focus on geographical redistribution of manufacturing facilities accommodation of a diversity of regulatory and statutory governance adaptation to disparate human resources and new growth areas of manufacture and distribution of homeopathic remedies and dietary supplements in addition to the greater quality control required of pharmacists and other authorized dispensers The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals José (Pepe) Rodríguez-Pérez, 2014-04-30 Good Manufacturing Practices GMP for human pharmaceuticals affects every patient taking a medicine GMP covers all aspects of the manufacturing process from defining manufacturing processes to systems for recall and investigation of complaints Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective GMPs provide for systems that assure proper design monitoring and control of manufacturing processes and facilities This formal system of controls at a pharmaceutical company if adequately put into practice helps to prevent instances of contamination mix ups deviations failures and errors This assures that drug products meet their quality standards This guidance book is meant as a resource to manufacturers of pharmaceuticals providing up to date information concerning required and recommended quality system practices It should be used as a companion to the regulations standards themselves and texts on the specific processes and activities contained within the QMS As a bonus this package contains dozens of FDA guidance documents as well as international harmonization documents WHO PIC S and ICH A check list for GMP audit is also included based on risk management criteria An exam complements the extra material Good Manufacturing Practices for Pharmaceuticals Sidney H. Willig, James R. Stoker, 1997 Revised to ensure GMP compliance this text examines US laws affecting domestic and multinational pharmaceutical manufacturing It recommends practical ways to interpret and comply with FDA CGMP regulations while meeting the goals of a comprehensive controls system to preserve product integrity FDA Compliance Program Guidance Manual United States. Food and Drug Administration, 1998-05-20

**Integrated Pharmaceutics** Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2022-09-07 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments

Integrated Pharmaceutics provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery. It presents its subject following the principles of physical pharmacy, product design, and drug regulations. This tripartite structure allows readers to move from theory to practice, beginning from a firm foundation of physical pharmacy principles including drug solubility and stability estimation, rheology, and interfacial properties. From there, it proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States, European Union, and Japan. Readers of the second edition of Integrated Pharmaceutics will also find a glossary defining key terms, extensive informative appendices, and a list of references leading to the primary literature in the field for each chapter. Earlier chapters are expanded with additional new chapters, including one entitled Biotechnology Products. Supplementary instructor guide with questions and solutions available online for registered professors. Updated regulatory guidelines including quality by design, design space analysis, process analytical technology, polymorphism, characterization, blend sample uniformity, and stability protocols. Integrated Pharmaceutics is a useful textbook for graduate students in pharmaceutical sciences, drug formulation and design, and biomedical engineering. In addition, professionals in the pharmaceutical industry, including regulatory bodies, will find it a helpful reference guide.

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