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# Equipment Hold-Time for Cleaning Validation

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*Regulatory agencies expect companies to establish and monitor clean equipment and dirty equipment hold times for manufacturing equipment as part of their cleaning validation programs.*

The concepts of "clean-hold time" and "dirty-hold time" have been part of cleaning validation since its inception. Clean hold time is generally considered to be the time between the completion of cleaning and the initiation of the subsequent manufacturing operation. Dirty hold time can begin when the clean equipment is initially soiled, but more often is defined as the time between the end of manufacturing and the beginning of the cleaning process. Intuitively, it makes sense to be concerned about both hold times. Dirty equipment is harder to clean the longer the hold time, and clean equipment has a greater chance of becoming soiled as hold time increases.

**Background**

In its Guide to Inspection of Validation of Cleaning Processes, the US Food and Drug Administration considers identifying and controlling the length of time between the end of processing and each cleaning step to be critical elements of the cleaning processes (1). FDA also expects pharmaceutical companies to demonstrate that routine cleaning and storage of equipment does not allow for microbial proliferation. The European Union expects companies to provide a validation master plan with clearly defined and documented validation program elements (2). Health Canada looks for companies to describe the interval between the end of production and the beginning of the cleaning procedures as well timeframes and conditions for the storage of clean equipment that do not allow for microbial proliferation (3). Finally, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) guideline looks for documentation of both dirty- and clean-hold times (4). The general practice among industry is to routinely document and track equipment hold times to ensure ongoing compliance.

Although regulatory agencies expect manufacturers to document and address hold times, they do not describe a process for establishing hold times. In this validation study, a dirty-hold time was established but ongoing implications were not examined (5). Several articles define both clean- and dirty-hold times and how to establish them but do not mention a strategy to guide the experiments (6, 7). A more recent article, which referred to hold-time studies as "the lost parameter for cleaning validation," explored several issues associated with hold-time studies (8). Issues included storage conditions, test locations, testing methodology, and the length of hold-time studies.

The concern with clean-hold times is that clean equipment will not stay clean indefinitely despite using appropriate storage conditions. Holding soiled equipment makes it more difficult to remove pharmaceutical soil and allows biological contamination to proliferate. To address these concerns, the author extended clean-hold time testing for more than 2 yrs and extended dirty-hold time studies for up to 9 days. After identifying clean- and dirty-hold time, ongoing control of the hold times became difficult. Every time a piece of equipment is used, the operator needs to confirm and document that the actual clean-hold time does not exceed the established clean-hold time. And before washing a piece of equipment, the washer needs to confirm and document that the actual dirty-hold time does not exceed the established dirty-hold time.

This study suggests that if clean- and dirty-hold time issues are addressed during the validation study that the severity of exceeding the established hold times diminishes to a near-acceptable level.

# Equipment Hold Time For Cleaning Validation

Raymond Spier

**Equipment Hold Time For Cleaning Validation:**

*Microbial Limit and Bioburden Tests* Lucia Clontz,2008-10-14 In recent years the field of pharmaceutical microbiology has experienced numerous technological advances accompanied by the publication of new and harmonized compendial methods It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical biopharmaceutical products to keep abreast of the latest c **WHO Expert Committee on Specifications for Pharmaceutical Preparations** ,2021-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools Standards are developed by the Expert Committee through worldwide consultation and an international consensus building process The following new guidance texts were adopted and recommended for use Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations Points to consider when including Health Based Exposure Limits HBELs in cleaning validation Good manufacturing practices water for pharmaceutical use Guideline on data integrity WHO United Nations Population Fund recommendations for condom storage and shipping temperatures WHO United Nations Population Fund guidance on testing of male latex condoms WHO United Nations Population Fund guidance on conducting post market surveillance of condoms WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release solid oral dosage forms WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce Good reliance practices in the regulation of medical products high level principles and considerations and Good regulatory practices in the regulations of medical products All of the above are included in this report and recommended for implementation

**Pharmaceutical Microbiological Quality Assurance and Control** David Roesti,Marcel Goverde,2019-12-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical companies and expert networks *WHO Drug Information* ,2021-02-18 Encyclopedia of Bioprocess Technology Michael C. Flickinger,Stephen W. Drew,1999 *Pharmaceutical Process Validation, Second Edition* Ira R. Berry,Robert A. Nash,1993-01-29 The second edition of this text has been updated and enlarged to reflect current good manufacturing practice CGMP regulations and the increased interest in and applicability of process validation Pharmaceutical Process Validation offers up to the minute coverage of regulations and validation sterile process validation organization in validation processes solid dosage forms validation raw material validation analytical methods validation and prospective and

retrospective validation Providing the contributions of leading experts in the field the text also supplies examinations of current concepts in validation and new topics such as validation of cleaning systems and computer systems equipment and water systems validation and lyophilized and aerosol product validation Handbook of Process Chromatography Gail K. Sofer,Lars Hagel,1997-06-24 This Handbook offers a practical approach to developing an optimal chromatographic process scaling it up and adapting it to comply with requirements set by world wide regulatory agencies The reader is led through every stage of the development process using examples from companies with established processes and approved biotherapeutics The aim is to help the reader to realize the scope of issues that must be evaluated and to avoid common pitfalls For the uninitiated separate chapters also deal with basic chromatography theory and properties of biological molecules The holistic and practical approach of the Handbook make it an essential reference for graduates and researchers in biochemical engineering and biotechnology as well as practitioners in the pharmaceutical industry The enclosed disk also makes the Handbook an excellent hands on teaching tool *Encyclopedia of Cell Technology* Raymond Spier,2000 Brings together up to date information on all key aspects of plant and animal cell technology in a single resource Covers scientific historical and ethical aspects of biotechnology Synthesizes a wealth of information in a valuable one stop resource Invaluable to researchers working animal or plant cell technology The Encyclopedia of Cell Technology Raymond Spier,2000-02-10 Brings together up to date information on all key aspects of plant and animal cell technology in a single resource Covers scientific historical and ethical aspects of biotechnology Synthesizes a wealth of information in a valuable one stop resource Invaluable to researchers working animal or plant cell technology New Scientist and Science Journal ,2003 *New Scientist* ,1999 **The Chemical Engineer** ,2008 **Manual of Industrial Microbiology and Biotechnology** Arnold L. Demain,Julian E. Davies,Ronald M. Atlas,1999 The editors have enlisted a broad range of experts including microbial ecologists physiologists geneticists biochemists molecular biologists and biochemical engineers who offer practical experience not found in texts and journals This comprehensive perspective makes MIMB a valuable how to resource the structure of which resembles the sequence of operation involved in the development of a commercial biological process and product Genetic Engineering News ,2007 **Genetic Engineering & Biotechnology News** ,2009

**Pharmaceutical Operations Management** Pankaj Mohan,Jarka Glassey,Gary A. Montague,2006-03-16 This book brings together a winning team of international operations experts to set the framework for building a world class manufacturing organization Pharmaceutical Operations Management focuses on key concepts such as Policy Execution Risk Management Supply chain modeling Advance process control and Six Sigma for the pharmaceutical industry critical techniques which will offset cost increase efficiency and turn any manufacture into financial winner *Technical Report Series* ,2018 Processing ,1999 Fishman's Pulmonary Diseases and Disorders, 2-Volume Set, Sixth Edition Michael A. Grippi,Danielle E. Antin-Ozerkis,Charles S. Dela Cruz,Robert Kotloff,Camille N. Kotton,Allan I. Pack,2022-10-22 The

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