

Critical temperature areas in a 2 - 8 °C warehouse for pharmaceuticals (example):



- 1 Near to window and skylight: 8.1 °C
- 2 Greatest distance to ventilation outlet: 7.5 °C
- 3 Close to door: temporarily up to 9.1 °C
- 4 Near to lamp: 6.5 °C
- 5 Directly at ventilation outlet: 2.4 °C

Qualification Of Temperature Controlled Storage Areas

World Health Organization



Qualification Of Temperature Controlled Storage Areas:

WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting, 2015-05-11 The World Health Organization WHO Expert Committee on Specifications for Pharmaceutical Preparations advises the Director General of WHO in the area of medicines quality assurance It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States Its advice is developed through a broad consensus building process and covers all areas of quality assurance of medicines from their development to their distribution to patients In the area of quality control the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines Annex 2 Updating mechanism for the section on radiopharmaceuticals in The International Pharmacopoeia revision Annex 3 Supplementary guidelines on good manufacturing practices validation Appendix 7 non sterile process validation revision Annex 4 General guidance for inspectors on hold time studies new Annex 6 Recommendations for quality requirements when plant derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients revision Annex 7 Guidelines on registration requirements to establish interchangeability revision Annex 8 Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource generic products revision Annex 9 Good review practices guidelines for regulatory authorities new In addition 16 technical supplements to the WHO model guidance for the storage and transport of time and temperature sensitive pharmaceutical products were adopted for publication in a format which is appropriate to the large volume of this guidance Annex 5 The newly adopted monographs were adopted for inclusion in The International Pharmacopoeia Following the implementation of the revised general monograph on parenteral preparations the Committee adopted the proposed endotoxin limits for 11 parenteral dosage form monographs lacking such specification together with related updates to relevant monographs The Committee adopted 12 ICRS newly characterized by the custodian centre EDQM The Committee further adopted the workplan for new monographs to be included in The International Pharmacopoeia

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials, tenth edition. Volume 1. Good practices and related regulatory guidance World Health

Organization, 2024-10-24 This publication represents a significant achievement in our ongoing effort to ensure that everyone can reach the highest possible level of health Over the last three decades we have seen the transformation of the pharmaceutical industry and the increasing intricacy of the product life cycle The challenges we face today are very different from those we faced when the first edition of this Compendium was published in 1997 However our mission remains the same to promote health keep the world safe and serve the vulnerable The new edition reflects the collective knowledge and expertise of countless professionals who have worked diligently to develop revise and implement WHO guidelines for

pharmaceuticals This includes experts from WHO Member States our Expert Advisory Panels and Expert Committees on Specifications for Pharmaceutical Preparations and other organizations and has undergone extensive consultation with stakeholders worldwide This Compendium covers development through manufacturing and quality control to post marketing surveillance It provides a comprehensive framework for quality assurance that is both strong and flexible capable of meeting the requirements of a rapidly changing global health landscape The 10th edition is a collection of knowledge and tools for empowerment enabling all stakeholders in the pharmaceutical industry to make informed decisions that prioritize patient safety and well being *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection* World Health Organization,2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization,2022-12-22 The WHO Technical Report Series 1044 presents the fifty sixth report by the WHO Expert Committee on the Specifications for Pharmaceutical Preparations It provides comprehensive standards and guidelines for the quality assurance of medicines developed through extensive international consultation The report includes new guidance on various aspects such as good manufacturing practices for sterile products technology transfer for medicinal gases and the stability studies of medical products The WHO s publications aim to support national health strategies and address pressing public health concerns by disseminating authoritative information and guidance globally This report reflects the collective views of international experts contributing to the WHO s mission to attain the highest possible level of health for all people Technical Report Series ,1950 **Handbook of Validation in Pharmaceutical Processes, Fourth Edition** James Agalloco,Phil DeSantis,Anthony Grilli,Anthony Pavell,2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry s leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and

identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture

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