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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1268-2023

Product adoption and process equivalence for ethylene oxide sterilization

环氧乙烷灭菌的产品追加和过程等效

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020 "Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents". This document replaces YY/T 1268-2015 "Product adoption and process equivalence for ethylene oxide sterilization". Compared with YY/T 1268-2015, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

a) Changed the scope statement (see Chapter 1 of this Edition; Chapter 1 of Edition 2015);

b) Changed the terms and definitions of "candidate equipment", "candidate product", "EO processing category", "EO product family", "load configuration", "process equivalence", "product adoption", "requalification", "sterilization process equipment" and "sterilization specialist" (see 3.1~3.5, 3.7~

3.11 of this Edition; 3.1~

3.10 of Edition 2015);

c) Added the term and definition "packaging system" (see

3.6 of this Edition);

d) Changed the additional notes for products in Chapter 4 to general provisions (see

4.1 of this Edition; Notes for Chapter 4 of Edition 2015);

e) Changed the contents of product family and processing category (see

4.2 of this Edition;

4.2 of Edition 2015);

f) Changed the mandatory clauses to recommended clauses (see 4.2, 4.3, 4.5, 4.7,

1 Scope

YY/T 1268 answers a question every sterilization manager faces: when can a new product be added to an already validated ethylene oxide cycle without validating from scratch, and when are two processes equivalent enough to transfer a validation between them. It sets out the criteria and the evidence needed for both, covering how a product family is defined, what makes a new item representative of one, and what has to be demonstrated when a cycle moves to a different chamber or load configuration. Full validation is expensive and slow, so this document is what makes a broad product range commercially viable. For a Chinese device manufacturer or a contract steriliser, this is the text an auditor applies when the sterilization file relies on adoption or equivalence rather than on a validation of its own.

This document specifies the requirements for adoption of new or changed products to a validated sterilization process for medical devices using ethylene oxide sterilization. It provides methods for evaluating the equivalence of sterilization processes when using different sterilization equipment. This document applies to medical devices sterilized with ethylene oxide using conventional release or parametric release. This document applies to ethylene oxide sterilization of medical devices including.

a) adding new products to a confirmed ethylene oxide sterilization process;

b) evaluating changes to confirmed products;

c) transferring a confirmed process to a different site or equipment;

d) evaluating the equivalence of sterilization processes.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 18279.1, Sterilization of health care products -- Ethylene oxide -- Part 1. Requirements for development, validation and routine control of a sterilization process for medical devices

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB 18279.1 as well as the followings apply.

3.1 candidate equipment New or modified equipment intended to perform an existing validated sterilization process.

3.4 EO product family A combination of products that are sterilized using the same process conditions and have similar or identical validation purposes are permitted.

3.5 load configuration The total properties of the product as it will behave during the sterilization process. This structure includes.

3.6 packaging system Combination of sterile barrier system and protective packaging.

3.7 process equivalence A written evaluation that the same sterilization process can be run within specified parameters on two or more sterilization process equipment.

3.8 product adoption The process of introducing a candidate product into an existing, identified EO processing category or family of ethylene oxide products.

3.9 requalification Partial validation activities performed to confirm the continuing conformity of a specified process.

3.10 sterilization process equipment Including preprocessing area (if used), sterilization cabinet or sterilization cabinet, aeration area (if used) and their respective auxiliary equipment.

4 Product adoption

4.1 General Product adoption is generally intended to simplify the performance qualification procedures required to introduce products into EO product family or EO processing category. The product adoption approach described in this document includes the establishment of EO product family and EO processing category and recommended practices for maintaining these product families and processing categories.

4.2 Product families and processing categories A product family is a group of products identified as having similar or identical confirmed purposes.

4.3 Determination of adverse product effects Before determining whether a candidate product or a candidate packaging system can be added to a product family or processing category, it shall be determined whether the candidate product or candidate packaging system still retains functionality and effectiveness. The design or change control process shall provide a system for evaluating these aspects.

4.4 Determination of impact on product design The design of the candidate product shall be carefully reviewed for changes that create a greater barrier to ethylene oxide gas, heat, or moisture penetration than the existing product or process challenge device. Examples of product changes are longer lumens, additional closures, or more bonding surfaces.

4.6 Determination of impact on sterile barrier system The candidate product's sterile barrier system shall be examined for factors that create barriers to the penetration of ethylene oxide, heat, or moisture. These factors could be reduced porosity of the permeable material, reduced permeable surface area, closed permeable surfaces, or any other feature that makes the candidate product more challenging to sterilize than existing products or process challenge devices. In addition, the potential impact of changes in the sterile barrier

system on the product's bioburden and ethylene oxide residuals shall be evaluated.

4.7 Determination of the impact on load configuration The loading pattern of the candidate product shall be carefully examined for any changes that could affect the thermodynamic response of the sterilization process. These changes could include the addition of more layers of wrap, reconfiguration of the tray, changes in load dimensions, changes in overall load density, or any other changes that would make the candidate product more challenging to sterilize.

4.9 Documents The decision on the analytical results that determine whether the candidate product can be added to the confirmed EO product family or EO processing category shall be documented. This document shall include at least the following.

5 Process equivalence

5.1 General Process equivalence is a method used to demonstrate that two or more pieces of equipment are capable of performing the same validated sterilization process. This does not require that the equipment be identical. Even if the parameters under which the equipment is run are statistically different, if the equipment has the ability to run the sterilization process within the specified validated range, the process is considered equivalent in that equipment.

5.2 Requirements for process equivalence Process equivalence can be established regardless of whether the equipment is located in the same location or in different locations. Before establishing a process equivalence program, the following requirements shall be met.

5.3 Determination of process equivalence Sterilization process equivalence between equipment is established by comparing data obtained from running the same validated process on each equipment separately. This comparison shall include an evaluation of the ability of the equipment to reproducibly achieve the expected process parameters when sterilizing routine production loads.

5.4 Process analysis and evaluation Perform data analysis related to the confirmed process for the candidate equipment and the initial equipment. Process data shall be collected from the candidate equipment. These data shall be compared with the parameter range of the specific sterilization process and the data obtained during the performance qualification process of the initial equipment.

5.5 Preprocessing or parsing area evaluation The requirements for preprocessing or establishing process equivalence in analytical area are the same. Usually there is no humidity requirement for the analytical area. An evaluation shall be performed to compare the temperature and humidity profiles of the load in each environment. At a minimum, the consistency of temperature and humidity within the load shall be evaluated and the relationship of this consistency to the corresponding set points and control ranges recorded