Status: Currently Official on 12-Feb-2025
Official Date: Official as of 01-Aug-2016
Document Type: General Chapter
DocId: GUID-768122F6-B56E-451C-BFAB-0352AF0E2F20_1_en-US
DOI: https://doi.org/10.31003/USPNF_M9836_01_01
DOI Ref: zzd1i

⟨1229.12⟩ NEW STERILIZATION METHODS

INTRODUCTION

Sterilization processes are developed for the elimination of viable microorganisms while preserving the essential physical, chemical, and biological properties of the materials subjected to them. Where this cannot be accomplished by the sterilization methods described in *Sterilization of Compendial Articles* ⟨1229⟩, it may be possible to sterilize by using a proposed method not commonly used. When doing so, it is the end user's responsibility to demonstrate that the proposed new method can be used safely and effectively.

POINTS TO CONSIDER FOR A NEW STERILIZATION METHOD

The major steps in the implementation of a new sterilization method include the following:

- Elimination of any established method through experimental evidence and/or comprehensive literature review of any materials used
- A literature review to identify supportive information on the proposed method
- Identification and confirmation of reproducible lethality against a broad range of microorganisms, including bacterial spore-formers
- Identification and definition of critical process parameters necessary to ensure sufficient lethality. The effective range of these parameters should be explored to identify necessary conditions for the proposed sterilization process. Among the parameters to be considered, depending upon the nature of the process under consideration, are process dwell time, temperature, concentration, energy or power, and relative humidity. This evaluation should include positive and negative controls to ensure that the proposed method is in fact responsible for microbial destruction.
- The selection of a biological indicator (usually a spore-forming microorganism) with increased resistance to the sterilization method
- Evaluation of the proposed method against anticipated bioburden microorganisms and comparison of relative resistance of the bioburden microorganism to that of the chosen biological indicator
- The identification of in-process and/or post-process measurements and/or analysis that can reliably confirm the effectiveness of the proposed sterilization process.

Where the proposed new method is used for materials intended for human and/or veterinary use, the relevant regulatory authorities should be contacted to secure their acceptance before either investigational or clinical usage. Validation of the proposed new method should be completed before use on a commercial basis.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
<1229.12> NEW STERILIZATION METHODS	Huiping Tu Director, Biologics	GCM2022 General Chapters - Microbiology 2022

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(2)

Current DocID: GUID-768122F6-B56E-451C-BFAB-0352AF0E2F20_1_en-US
DOI: https://doi.org/10.31003/USPNF_M9836_01_01
DOI ref: zzd1i