

TECHNOTES

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Texwipe Sterile Products

Sterilized, Validated,
Documented and
Endotoxin Tested

Texwipe Sterile Products follow the AAMI/ISO 11137 guidelines concerning sterilization validation by radiation and the current version requirements of the USP <161> for endotoxin testing.



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Introduction

Texwipe developed a line of sterile products (dry and pre-wetted wipers, IPA solutions, mops and swabs) for cleaning sterile environments quickly and easily, without compromising the sterile nature of those environments.

Although Texwipe's products are not medical devices, Texwipe has chosen to follow the guidelines of the Association for the Advancement of Medical Instrumentation (AAMI) concerning the validation of radiation sterilization and the requirements of the current version of the United States Pharmacopeia (USP) <161> *Transfusion and Infusion Assemblies and Similar Medical Devices for irradiation steps and endotoxin testing*.

Sterilization, Validation, Documentation

Texwipe sterile products are irradiated. Texwipe has chosen irradiation over other sterilization techniques for the following reasons:

1. Irradiation sterilization is a relatively easy process to validate. This is especially important because Texwipe sterile products adhere to the AAMI/ISO 11137 standard.

2. Irradiation sterilization leaves no residues from treatment.

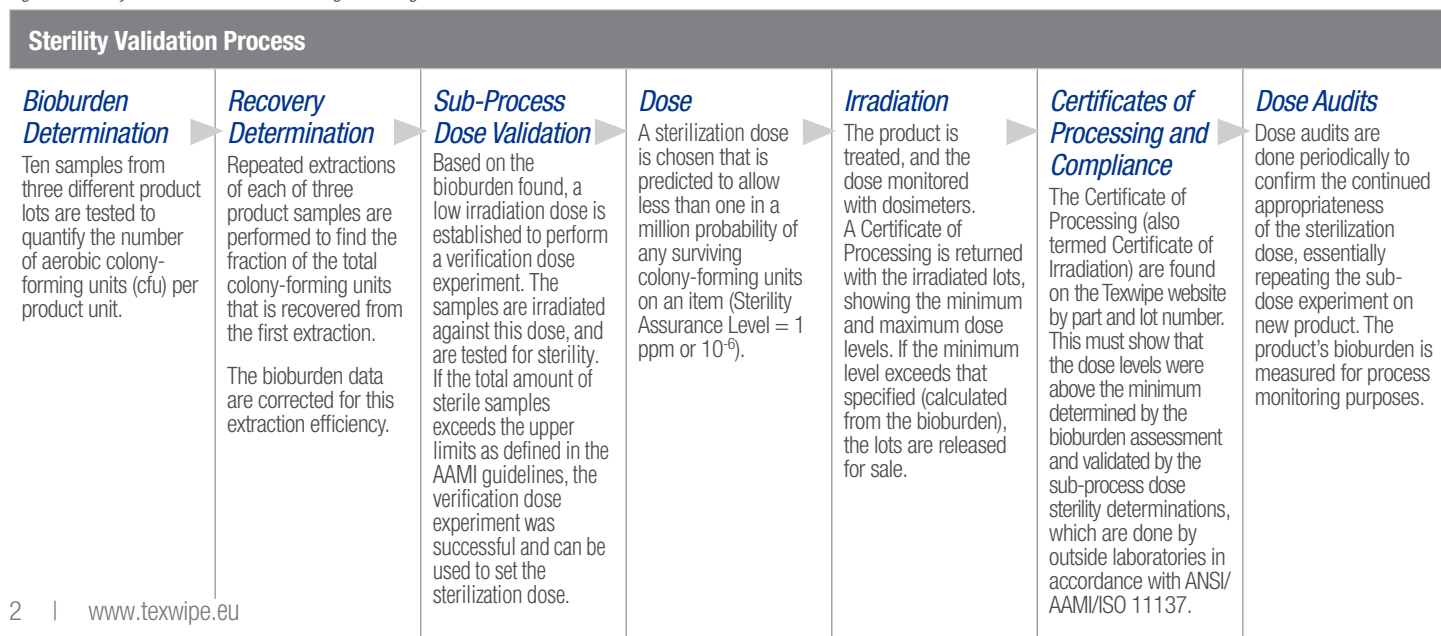
3. Irradiation sterilization is compatible with many of the wiper materials and solutions used in Texwipe products.

Validation Process Overview

Since Texwipe sterile products are sterilized according to AAMI guidelines for the validation of radiation sterilization, a strict processing regimen is followed. Products are tested for bioburden, and the data are corrected for recovery. From the corrected bioburden data, a verification dose is determined. A verification dose experiment is performed to ensure that there are no unusually radiation-resistant bacterial strains present.

Once the dose verification is accepted, products are irradiated at the dose determined by the bioburden and confirmed by the dose validation. All irradiated products are supplied with a Certificate of Processing. The flow chart (Figure 1) describes these steps in more detail.

Figure 1 Sterility Validation Process according to AAMI guidelines



Endotoxin Testing

Bacterial endotoxins are fever-causing materials from the outer cell membranes of Gram-negative bacteria. Most bacteria found in clean water are Gram-negative. When the bacteria die, endotoxin is released into the water. An example of Gram-negative bacteria that we are all familiar with is *E. coli*, often found in contaminated water. Minute levels of these bacterial toxins are associated with certain bacterial diseases and the production of fever, shock, and death in humans and animals.

Removing endotoxins from contaminated product samples is extremely difficult. Sterilization techniques kill living organisms, and since endotoxins come from dead cells, standard sterilization techniques, with few exceptions, are not effective in reducing endotoxin levels. Prevention of bacterial contamination is the best course of action to ensure high quality products. Therefore, it is essential to ensure that the materials used during the production of the parenteral drug or medical device do not contribute to the pyrogen levels.

The allowable limits of endotoxins in human and animal parenteral drugs, biological products and medical devices are established by the FDA. Texwipe sterile products conform to the requirements of the current version of the USP <161>, Transfusion and Infusion Assemblies and Similar Medical Devices. This limit, applied to devices in contact, either directly or indirectly, with the cardiovascular system or lymphatic system, has been set at less than 20 endotoxin units/device (<20 EU/device).

Further, a validation assay is performed in the following manner:

1. The reagent is tested against an endotoxin standard, with serial dilutions.
2. The extracts are tested to assure they do not inhibit or enhance the formation of the gel when endotoxins are present.
3. This validation assay is performed in quadruplicate.

Endotoxin Test Results

Although Texwipe's sterile products are not considered medical devices and are not required to conform to the current version of the USP standards, the test results indicate that all Texwipe sterile products do meet a standard of <20 Endotoxin Units. The endotoxin test results are available for each sterile product upon request.

Test Method

The widely used assay method for bacterial endotoxins is based on the blood cell extract, or amebocyte, from the horseshoe crab (*Limulus polyphemus*). Much like a human donates blood, the horseshoe crab "donates" some of its blood, which is broken down into its components, plasma and amebocytes. The LAL (Limulus amebocyte lysate) reagent is produced by lysis (rupture) of these amebocytes. The LAL reagent is a mixture of proteins and salts whose origin is the amebocyte. The LAL test is an effective measure of endotoxin levels as it is extremely sensitive. The gel clot test is capable of detecting endotoxin levels as low as 0.005 EU/mL (about 0.0005 ng/mL or 0.0005 parts per billion).

As outlined in the current version of the USP, the test method includes the following steps:

1. Between three and ten wipers are extracted with LAL Quality Water (USP Water for Injection).
2. A standardized LAL reagent is mixed with the test samples and heated.
3. A firm gel is formed if the concentration of endotoxin exceeds the reagent labeled sensitivity.



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Conclusion

Texwipe's sterile products are irradiated to the Sterility Assurance Level of 10^{-6} in accordance with AAMI standards and are tested for endotoxin levels per the current version of the USP <161>. This ensures the highest quality of products available for cleaning and disinfection of equipment and environmental surfaces under sterile conditions. These products are ideal for cleaning pharmaceutical aseptic filling areas, sterile suites, prep rooms, microbiological laboratories, and biotech manufacturing facilities, anywhere sterile products are made and the area must remain sterile.

For additional information, please contact Texwipe Customer Service at the number listed below.

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