Aseptic Considerations for Life Science Containers

APPLICATION NOTE

SAVILLEX | 10321 W. 70TH ST., EDEN PRAIRIE, MN, 55344
INFO@SAVILLEX.COM | 952.935.4100
WWW.SAVILLEX.COM

Savillex

APPLICATION NOTE

Aseptic Considerations for Life Science Containers

ABSTRACT

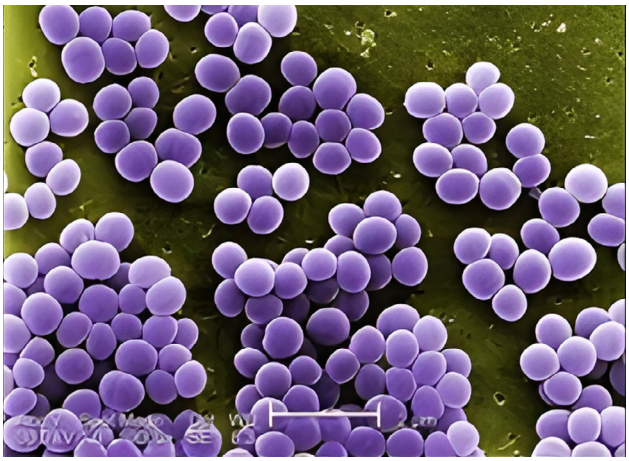


Figure 1: Staphylococcus aureus

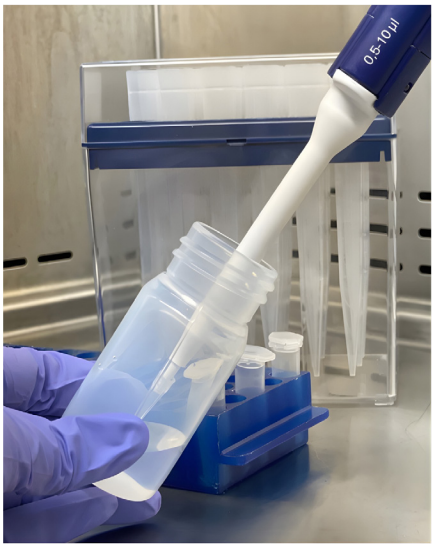
The term aseptic means “free of contamination from bacteria, viruses, or other microorganisms”. Although sterilization processes like autoclaving and gamma irradiation can eliminate viable microbes, they can only do so as a consistent, validated process if the baseline bioburden is below a pre-set limit.

Certain microorganisms, even though killed thus no longer viable, can leave behind contamination in the form of endotoxins. Even very small contaminations by some organisms can lead to unacceptable endotoxin levels. RNase, an enzyme that breaks down RNA, and DNase, which breaks down DNA, are other biological contaminants that can interfere with nucleotide research. Micrococcal nuclease (MNase) is an enzyme extracellular nuclease of Staphylococcus aureus, a common environmental bacterium, and can be released when the organism is killed (shown in Figure 1).

A critically important part of Savillex’s container manufacturing process is avoiding contamination from microbial sources. To this end, proper care must be taken to maintain an aseptic production environment, including the use of cleanroom space during critical steps. Furthermore, personnel must be appropriately gowned and wear gloves near part manufacturing, as humans are a significant source of microbes. The finished product is also handled and packaged in a way to ensure cleanliness.

Savillex’s Purillex® range of fluoropolymer bottles, vials, and jars are the ideal containers for use in life science aseptic processes. The container material itself provides non-stick properties and has surface characteristics that are not conducive to microbial survival and propagation. Additionally, the exceptionally high temperatures used to process fluoropolymers during container manufacturing - and the amount of time the material is at these high temperatures - essentially eliminates all microbes and microbial contamination.

Products can be tested for microbial contamination using several methods. This application note outlines three methods used to test Savillex Purillex PFA containers to ensure they are free from harmful microbial organisms and microbial byproducts.



Testing for microbial contamination

TEST METHOD 1 - BIOBURDEN

Bioburden testing measures the total viable count of microbial contamination on the wetted surface of a product container. Bioburden can be used as a routine product quality test for non-sterile products and can also be used to ensure that sterilization methods remain adequate for terminally sterilized products. In addition, the bioburden testing method can give total viable counts and be used to identify the presence or absence of specified microorganisms of concern.

Bioburden can be introduced to a product through raw materials, manufacturing equipment, product handling, storage, packaging, or any step where personnel is present. Bioburden testing should be performed on a regular basis. For example, Savillex performs bioburden testing on every lot of RTU products to be terminally sterilized. It is also critical that bioburden recovery and testing methods are developed and validated for each product type, size, and configuration. Savillex provides this information in a product validation binder, available upon request.

TEST METHOD 2 - ENDOTOXIN

Endotoxin is a type of pyrogen which directly results from gram-negative microbes that are the most common cause of toxic reactions due to microbial contamination. Most gram-negative organisms are water-borne, meaning that this test is critical for any products that come into contact with water or other significant sources of moisture throughout manufacturing, handling, storage, or shipping processes. The USP <85> Bacterial Endotoxins Test uses Limulus Amoebocyte Lysate (LAL) derived from the blood of horseshoe crabs, which clots in the presence of endotoxin (shown in Figure 2).

At Savillex, our Purillex containers are manufactured without the use of water, thus eliminating the most common source of endotoxin contamination.

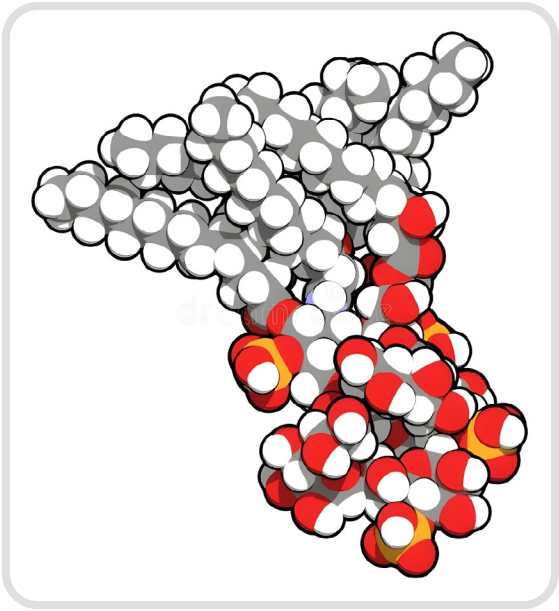


Figure 2: Endotoxin molecule

For more application notes covering our line of Purillex containers, please click here to visit our online Resource Library

TEST METHOD 3 - ENZYME TESTING

Like endotoxin, DNase, RNase, and other enzymes are byproducts of bacterial contamination and can also come from human sources. Rapid detection assays for enzymes use reagents, which are fluorescence-quenched oligonucleotide probes that emit a fluorescence signal only after nuclease degradation. This fluorescence can then be detected, and the concentration of RNase and DNase quantified using fluorometry. Another method is gel electrophoresis, where known concentration standards are used to determine the contamination level.

Savillex Purillex container materials are certified to be DNase and RNase-free.

CONCLUSION

Container cleanliness is critical for aseptic applications - particularly for pre-sterilized ready-to-use (RTU) products like bottles, vials, and jars. Therefore, the three testing methods outlined in this technical note are routinely performed on Purillex containers to ensure they are free from microbial contamination and suitable for the most critical life science applications.

CLICK HERE TO LEARN MORE ABOUT PURILLEX BOTTLES AND PLACE ORDERS ONLINE.

Savillex 10321 W. 70th St. | Eden Prairie, MN, 55344-3446 USA
Phone: 952.935.4100 | Email: info@savillex.com | www.savillex.com