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Technical Bulletin

The BIOEAZE™ Drop Test: Impact Resistance of Water-Filled PE (Polyethylene) Bioprocess Bags at Different Temperatures

Introduction

SAFC Biosciences' BIOEAZE™ disposable bioprocess bags are used as flexible storage containers for cell culture media, water, buffers and other solutions used in the pharmaceutical and biotechnology industries. These bags have been designed to provide strong seals, extraordinary robustness, superior flex and crack and pin-hole resistance. The BIOEAZE™ Drop Test is a physical challenge intended to determine the impact resistance of BIOEAZE™ bags. The test is intended to mimic a typical mishap during routine handling, such as a bag being dropped or falling off a laboratory bench. The drop test is a simple pass/fail test, with a failure considered to be any type of leakage occurring due to a breakage of the bag film, a burst or separation along the seam or leakage at the connectors. No evidence of leakage is considered a pass.

In this study, sterilized (gamma irradiated) polyethylene (PE) bioprocess bags were filled with a colored water solution, acclimatized to various temperatures and dropped from a height of 3.5 feet (107 cm). The test concluded that 1 L PE bags containing frozen, refrigerated, room temperature and 37 C solutions did not leak when dropped from a height of 3.5 feet. However, 20 L bioprocess bags were likely to experience a failure when dropped. This indicates that handling solutions in PE bioprocess bags, as with all containers, should be done with caution to avoid compromising container integrity and product quality. The information obtained from these tests is to be used for reference purposes only.

Materials

- 1 L PE Bag, SAFC Biosciences, Catalog No. 1334B
- 20 L PE Bag, SAFC Biosciences, Item No. 3518B
- Phenol Red, SAFC Biosciences, Catalog No. 59415
- C-Flex® Tubing, Consolidated Polymer Technologies, Inc. , Product No. 190-730-001
- Peristaltic Pump, Cole-Parmer Instrument Company, Model No. 7549-39.

Methods

Twelve PE bioprocess bags for each size category were filled with a water/phenol red mixture to allow easier visualization of leaks. The bags were filled to SAFC Biosciences' predetermined volume levels and inspected to ensure that there were no leaks prior to the test. Each bag was then placed in a plastic tote for storage. Triplicate bags for each size were placed in a freezer (-10 to -20 C), a refrigerator (2 to 8 C), an area of the laboratory at ambient temperature and a 37 C incubator.

The bags were allowed to acclimatize for 48 hours at each temperature and were removed from the storage areas. Within 15 minutes of removal, the bags were dropped from a height of 3.5 feet (approximately 107 cm). The bags were immediately examined for obvious leaks or seepage or any other signs of a compromise in product quality (e.g. cracking or shattering). Bags that had been frozen were subsequently allowed to thaw and again checked for leaks. All bags were placed back into totes, stored at room temperature and inspected again one week later for leaks.

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Results

Table 1 shows the individual results of each bag. No leaks were observed in any of the 1 L PE bioprocess bags at any temperature, with the exception of Bag 3 in the -10 to -20 C test. This bag inadvertently struck a piece of laboratory equipment during the test and was excluded from the study.

The 20 L PE bags experienced more leaks than the 1 L PE bags. No leaks were observed in the ambient temperature experiment; however, one third of the bags stored at 37 C and 2 to 8 C experienced a leak. All bags that contained a frozen solution showed evidence of leakage.

Conclusion

These results indicate that 20 L PE bags are susceptible to leakage when filled with solutions that differ from ambient temperature and are dropped from a height of 3.5 feet. In contrast, it appears that 1 L PE bags can withstand a drop from a height of 3.5 feet when filled with solutions which range in temperature from -20 to 37 C. It must be stressed however, that care must be exercised when handling all containers to avoid a compromise in container integrity and product quality.

Table 1. Observed Leaks in PE Bioprocess Bags

Size	Bag Number	37 C	Ambient	2 to 8 C	-10 to -20 C
1 L PE Bag	1	Pass	Pass	Pass	Pass
	2	Pass	Pass	Pass	Pass
	3	Pass	Pass	Pass	N/A*
20 L PE Bag	1	Fail	Pass	Pass	Fail
	2	Pass	Pass	Fail	Fail
	3	Pass	Pass	Pass	Fail

*This bag was excluded from the study.

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