

TECHNOTES

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An ITW Company

Integrity Test Results for
**Bags Used as a
Component**
of Sterile 70% IPA, TexQ Disinfectant and
TexP peroxide solutions ►

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Integrity Test Results for Bags Used as a Component

Sterile 70% IPA, TexQ Disinfectant and TexP Peroxide Solutions

Introduction

The sterile 70% isopropyl alcohol (IPA) products (TX3270 and TX3290) and TexQ™ disinfectant products (TX650, TX650M and TX651) are double bagged to allow these products to be brought from the warehouse into an aseptic area for use. The TexP™ peroxide products (TX684, TX684G, TX687, and TX687G) are also double bagged to reduce the risk of contamination that may be brought into critical area from outer environments.

The sequence of double-bagged containers introduction into critical area consists of several steps:

1. Remove the double-bagged product from the case
2. Wipe the outside of outside bag with a 70% isopropyl alcohol pre-wetted wiper
3. Place the product into a pass-through and close the door
4. Remove the product from the pass-through and remove the outer bag of the product
5. Place the product into the next pass-through that may enter into the aseptic area

The sequence listed above may vary from a company's standard operating procedure. It is recommended that the company standard operating procedure be followed at all times.

For sterile products, the product sterility is protected by the two sealed bags surrounding the individual bottle. To ensure sterility of the product and continued protection of the aseptic cleanroom from microbial contamination, the bags surrounding the product must not open during shipping and handling. A bag integrity test is used to confirm the seal strength of the bags surrounding the sterile product.

Test Objective

The objective of the bag integrity test is to demonstrate the bag's seal strength and its resistance to breaking or bursting.

The tested bags are used as a product component for:

1. Sterile 70% IPA: TX3270, TX3274, TX3290
2. TexQ Disinfectant: TX650, TX650M, TX651
3. TexP Peroxide Solution: TX684, TX684G, TX687, TX687G



Test Method

Texwipe's bag seals are tested through inflating the bag with pressurized air on a BT-1000 Burst Tester manufactured by T. M. Electronics, Inc., Worcester, Massachusetts, USA, until the bags burst. The resulting pressure reading is used to assess the strength of the seal.

Test Procedure

To perform the test a pair of scissors is used to cut open the entire length of one of the bag manufacturer's seals on a sealed bag. The open end of the bag is slid between the rubber jaws of the Open Package Fixture, and the air supply port is confirmed to be inserted into the bag. The bag is fixed in place by a clamp that also allows the test to proceed. Once the bag is in place, the analyzer is activated. Air enters the sealed bag until it bursts. The pressure is read on the instrument and recorded. A pressure greater than ten inches of water (in H₂O) or 2.49 kilopascals (kPa) is considered passing.

Nine bags were tested using the procedure described above. The bag integrity test results are compiled in Table 1. The units of pressure were recorded initially in inches of water for the test and were later converted to kilopascals.

Results

Table 1 Bag Integrity Test Results

Sample Number	PB3270		PB3290	
	(in H ₂ O)	(kPa)	(in H ₂ O)	(kPa)
1	69.5	17.31	30.5	7.60
2	70	17.44	30	7.47
3	70.5	17.56	30.5	7.60
4	70	17.44	30	7.47
5	69.5	17.31	30	7.47
6	69.5	17.31	30	7.47
7	69.5	17.31	29.5	7.35
8	69.5	17.31	29.5	7.35
9	69.5	17.31	30.5	7.60
Average	69.7	17.37	30.1	7.49
St. Dev.	0.36	0.09	0.39	0.10

PB3270 is the bag used for TX3270, TX3274, TX650, TX650M, TX684, and TX687.

PB3290 is the bag used for TX3290, TX651, TX684G, and TX687G.

St. Dev. is the standard deviation.

Conclusion

In review of the compiled bag integrity test results, the burst pressure for all of the bags was above the 10 in H₂O (2.49 kPa) limit. All bags successfully passed the bag integrity test.

For additional information, please contact
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