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Veripac Pti-325 versus Bonfiglioli LF-v Leak Tester Comparison

Performed According to

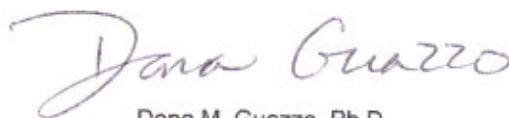
ASTM F2338-05

*"Standard Test Method for Nondestructive Detection of
Leaks in Packages by Vacuum Decay Method"*

Summary

A standard method for leak testing packages is described in ASTM F2338-05 "*Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method.*" The Veripac Pti-325 (manufactured by Package Technologies & Inspection, LLC) was used in the round robin studies performed during the preparation of this ASTM method. The ASTM studies demonstrated the instrument's ability to detect leaks in rigid packages of approximately 5 microns in size. The present study compared the Bonfiglioli LF-v vacuum decay leak tester (manufactured by Bonfiglioli Engineering) to the Veripac Pti-325 for its ability to also detect microleaks using the same total test time and initial vacuum setting for a rigid parenteral vial package. The results demonstrate that both instruments perform comparably in their ability to detect leaks of at least 0.35 cc/min (approximately 5.8×10^{-3} cc/s) given an initial test vacuum of 750 mbar.

Prepared by



Dana M. Guazzo, Ph.D.
RxPax, LLC
May 29, 2006

Support for this research was provided by Packaging Technologies & Inspection, LLC, Tuckahoe, NY 10707.

1. Introduction

The Veripac Pti-325 is a leak testing instrument manufactured by Package Technologies & Inspection, LLC of Tuckahoe, NY (PTI). This instrument model was used in the round robin studies performed during the preparation of ASTM F2338-05 "*Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method.*" These ASTM round robin studies demonstrated that the Pti-325 is capable of repeatably and reliably detecting leaks in a rigid container of at least 5 microns in size. These data are summarized in the ASTM method itself.

On May 1, 2006, a study was performed comparing the Pti-325 to a second vacuum decay leak testing instrument to evaluate its ability to also detect micro leaks according to ASTM F2338-05. The instrument evaluated was the Bonfiglioli LF-v vacuum decay leak tester (of Bonfiglioli Engineering, Italy). The package tested was a 20 mL parenteral vial package. The study was performed at Whitehouse Analytical Laboratories, LLC, a GMP package testing laboratory located in Whitehouse, NJ. All tests were performed under the supervision of Dana Guazzo, Ph.D. of RxPax, LLC, an independent package development consultant.

2. Purpose

The purpose of the study was to compare the Bonfiglioli LF-v vacuum decay leak tester to the Pti-325 leak tester for its ability to detect microleaks in a parenteral vial package. In order to directly compare the two instruments, the same test fixture, control package and test packages were used. In addition, test parameters of initial vacuum and total test time were matched.

3. Acceptance Criteria

The Bonfiglioli LF-v instrument is comparable to the Pti-325 if the following criteria are met.

All MASTER (nonleaking) tests PASS

All MASTER tests with the introduction of a 0.34 ccm calibrated leak FAIL

All Defective Leaking Package tests FAIL

4. Instrument Identification

Leak tester 1

Manufacturer	Packaging Technologies & Inspection, LLC 145 Main Street Tuckahoe, NY, USA 10707 www.ptiusa.com
Model	Veripac Pti-325
Serial Number	0102299PTI
Software Revision	224aPTI

Leak tester 2

Manufacturer	Bonfiglioli Engineering Via Rondona, 33 44018 – Vigarano Pieve Ferrara, Italy
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Model	www.bonfigliolipharma.com
Serial Number	Bonfiglioli LF-v
Software Revision	2495
	Version 1.0 DS2495 2006

Test chamber

Manufacturer	Bonfiglioli Engineering
Serial Numbers	3.31.00.00965

Microcalibrator

Manufacturer	Furness Controls, Inc. 2020 Younts Road Indian Trail, NC, USA 28079 www.furnesscontrols.com
Serial Number	040-8180

5. Test Sample Identification**Control, nonleaking sample**

20 mL MASTER (all stainless steel vial model)

Defective, leaking samples

20 mL glass vial, elastomeric stopper, aluminum seal
 Package 1: 100- μ m film placed between stopper/vial
 Package 2: Lactose placed between stopper/vial

6. Logistics**Testing location**

Whitehouse Analytical Laboratories
 291 Route 22 East
 Salem Industrial Park #4
 Whitehouse, NJ, USA 08888
 Phone 877-823-9300 (877-TEST LAB)
 Web www.whiteouselabs.com

Independent testing supervisor

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Date

Testing was performed May 1, 2006.

7. Procedures

- Test parameters used for conducting the leak tests are listed in Table 1. Test parameter terminology used for each instrument is reflected in the table. The goal was to match the initial target vacuum and the total testing time as closely as possible, given the inherent differences in instrument programming options and operating principles.
- Using the Veripac Pti-325, the leak rate of the MASTER was measured for 10 replicate tests. This was followed by 10 replicates with the introduction of a target leak rate of 0.34 ccm (0.33 to 0.35 ccm) using the Microcalibrator calibrated leak. Subsequently the two leaking vials were

also tested (duplicate readings for each vial). Data were recorded using an electronic Pti datasheet.

- Using the Bonfiglioli LF-v, the same tests performed using the Pti-325 were repeated. The data on the instrument display panel were manually recorded.

Table 1 Test Parameters and Specifications

Veripac Pti-325		Bonfiglioli LF-v	
Vacuum	750 mbar	Vacuum	750 mbar
Ref Vacuum	725.2 mbar	Minimum vacuum	720 mbar
TFill	0.60 s	Vacuum time	1.0 s
TEqual	10.00 s	1 st Reading	4.0 s
TTest	5.00 s	2 nd Reading	10.0 s
Ref dP/dt	3.9 Pa/s	Threshold	2 mbar

8. Results

Test results are summarized in Table 2.

Table 2 Test Results

Test Sample ID	Veripac Pti-325	Bonfiglioli LF-v
Master – no leak 10 replicates	10 PASS 0 FAIL	10 PASS 0 FAIL
Master – 0.34ccm leak 10 replicates	0 PASS 10 FAIL	0 PASS 10 FAIL
Test vial 1 – 100 µm film 2 replicates	0 PASS 2 FAIL	0 PASS 2 FAIL
Test vial 2 – Lactose 2 replicates	0 PASS 2 FAIL	0 PASS 2 FAIL

The data meet all acceptance criteria. For both the Veripac Pti-325 and the Bonfiglioli LF-v instruments,

All MASTER (nonleaking) tests PASS

All MASTER tests with the introduction of a 0.34 ccm calibrated leak FAIL

All Defective Leaking Package tests FAIL

9. Conclusion

The Veripac Pti-325 and the Bonfiglioli LF-v instruments provide comparable test results. Both instruments are capable of reliably detecting leaks of at least 0.35 cc/min (approximately 5.8×10^{-3} cc/s) given an initial test vacuum of 750 mbar.