Bonfiglioli Engineering
Quality Control Solutions

TASI GROUP

Quality Management System Nr 50 100 10979

PHARMACEUTICAL

PK-A

Off-Line Rotative Leak Testing Machine

- The Machine is designed for Non-Destructive Integrity Testing of Containers with pharmaceutical products.
- The Machine is suitable for 100% off-line testing at high production speed.
- The Measurement System comprises applying a pressure differential into an airtight Testing Group enclosing the Container (Patent No. 1225063 of 13-9-1988). The test objective is to detect Container leakages by measuring the reached pressure level as well as the pressure change over test time.
- The Measurement System follows the approved industry standard ''ASTM F2338-09'':
> ''Standard Test Method for Non-Destructive Detection of Leaks in Packages''
> The Test method is a Recognised Consensus Standard by the United States Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), effective March 31, 2006 (Reference: Federal Register Notice FR Notice (list #014) [Docket No. 2004N-0226]

Key Objectives and Benefits

- Containers automated loading and unloading.
- High leak detection sensitivity.
- Fast, reliable and repeatable results.
- Non-invasive and Non-destructive Test Method.
- Enhanced easy-to-use HMI integrated functions.
- System auto-diagnostics available.
- Easy to clean – no hidden corners.
- Ease of maintenance: free access to all moving parts.
- Cost-effective solution.
- Quick change over.
- Storage, maintenance, and download of historical data (production, raw data, events, alarms).
- HMI Real Time display of Testing Cycle diagram.
- Computerised system is designed to comply with FDA 21 CFR Part 11 and EU Annex 11.
- Validation Package guarantees complete and efficient regulatory compliance.

Technical Specifications

Tested Container	Vials, Ampoules .
Container Filling	Filled.
Container Content	Lyophilised, Liquid, Powder, Semi-solid.
Machine Type	Rotative Leak Tester.
Testing Methods	Vacuum Decay, Pressure Decay.
Max speed	Cpm
Min Container Dimension	10 x 10 x 35 mm (LxWxH)
Max Container Dimension	25 x 25 x 138 mm (LxWxH)
Testing Heads Number	18 to 36

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