

MC-D73 POSITIVE & NEGATIVE PRESSURE LEAK DETECTOR

SUITABLE FOR DYE INGRESS OR MICROBIAL INGRESS



COMPLIES WITH THE REVIEW STANDARDS OF INTERNATIONAL REGULATORY AUTHORITIES

EQUIPMENT INTRODUCTION

The MC-D73 is specifically designed for sealing performance testing in the pharmaceutical industry that requires vacuuming or pressurization, such as dye ingress or microbial ingress method, and is suitable for sealing performance tests for various packaging containers such as vials, ampoules, eye dropper bottles, BFS, IV bags and pre-filled syringes.

TEST PRINCIPLES

- Dye Ingress:**

Sealed containers are submerged in a concentrated dye solution and subjected to a pressure differential. If a leak pathway exists, the dye solution is driven into the container. After testing, the container is opened, and the interior is inspected visually or by UV spectrophotometry for dye presence.

- Microbial Ingress:**

Sealed containers are exposed to a high-concentration microbial challenge suspension under a defined pressure differential. After exposure, the container exterior is decontaminated, and the interior is tested for microbial growth. If viable microorganisms penetrate a leak pathway and are recovered from inside the container, the closure system has demonstrably failed to protect sterility.

EQUIPMENT FEATURES

- Dual System Control: Automatic switching between Negative Pressure and Positive Pressure modes without manual valve reconfiguration
- Method-Specific Design: Optimized exclusively for Dye Ingress and Microbial Ingress testing per pharmacopeial recommendations
- Standalone Operation: Configurable with an integrated vacuum pump and air compressor; no external plant air supply required (optional configuration)
- Altitude Simulation Capability: Adjustable negative pressure range allows for simulation of high-altitude air transport conditions as part of distribution challenge studies
- Broad Vessel Compatibility: Standard 20L chamber with customizable stainless steel racks to accommodate various container sizes and formats

TECHNICAL SPECIFICATIONS

Pressure Range	Approx. 113 - 4000 mbar (Absolute) – Wider custom ranges available
Chamber Volume	20 L
Pressure Control	Automatic switching between positive and negative pressure
Instrument Display	Digital Pressure Gauge
Certification	TUV
Validation Package	IQ/OQ Protocol Support
Dimension	Diameter 430 mm × Height 430 mm (Custom dimensions available)
Weight	24 kg (Unloaded)



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