

MC-H52 HELIUM LEAK DETECTOR

ONE OF THE MOST SENSITIVE CCIT METHODS



COMPLIES WITH THE REVIEW STANDARDS OF INTERNATIONAL REGULATORY AUTHORITIES

EQUIPMENT INTRODUCTION

The MC-H52 incorporates a highly sensitive mass spectrometer detector. It can be equipped with 21 CFR Part 11-compliant software for full data traceability and secure electronic records, ensuring data integrity. It is an ideal tool for pharmaceutical R&D, QC, and production sampling.

TEST PRINCIPLE

A package pre-filled with helium is placed in a custom test chamber. The chamber is evacuated, creating a pressure differential. Helium escaping through any leak is detected by the integrated mass spectrometer, which converts the signal into a quantitative helium leak rate displayed on the interface. A result exceeding a pre-set threshold indicates a package failure.

APPLICATION OBJECTS

- Package Development & Verification: Packageing system development, packaging integrity component inspection
- Storage & Transport: CCIT verification against integrity challenges in low temperature

EQUIPMENT FEATURES

- Exceptional sensitivity capable of detecting leaks below 0.1 μm
- Custom fixtures available for targeted testing of specific package areas
- Uses inert helium gas, ensuring safety and preventing chemical interactions
- Simple operation: connect the test chamber or use the sniffer probe to begin. Automated data display and logging post-test
- Complies with USP <1207> and USP <382> requirements

TECHNICAL SPECIFICATIONS

Application	Package design/development testing, mold qualification, line setup, ongoing product quality monitoring.
Minimum Detectable Leak Rate	1×10^{-10} mbar-L/sec
Software	Optional FDA 21 CFR Part 11 compliant software for data integrity
Options	Validation Package (IQ/OQ) available
Dimension	781 × 642 × 1153 mm (LxWxH)
Weight	21 kg
Power Supply	100-240 VAC, 50/60 Hz



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