





# 药品包装密封完整性测试 防止水分、氧气、微生物污染产品

- 符合ASTM F2338标准
- 半自动检测,适用于小批量、多品种测试
- 一台仪器可同时用于真空和正压检测
- 💿 检测结果可显示为Pa、Pa.m<sup>3</sup>/s和缺陷孔径μm
- 💿 检测结果数据库存储,便于质量管理
- ◎ 仪器具有真空汽化吹扫功能
- 🕥 采用压缩空气检测,使用成本低





## Integrity testing of pharmaceutical package encapsulation Prevent moisture, oxygen and microorganism from contaminating products

- Comply with ASTM F2338 standard
- Semi-automatic detection, suitable for small batch and multi-variety testing
- One instrument can be used for both vacuum and positive pressure test
- Test results can be shown as Pa, Pa.m<sup>3</sup>/s and µm of drilled defects
- Database storage of test results for the convenience of quality management
- The device has the function of vacuum vaporization and purging
- Compressed air detection, low cost of use

## 密封品差压检漏原理 Principle of differential pressure leak test of sealed products

仪器采用被测物、基准物差压比较方式,可以利用差压传感器的高灵敏 度检测出很微小的泄漏。检测时将工件放入密封容器内充压或抽真空,如工 件有小泄漏,那么密封容器中压力会发生变化,从而检出小泄漏;如果工件 存在大泄漏,充气时气体即充满工件内腔,此时采用大泄漏检测单元检出大 泄漏。

By adopting the way of comparing differential pressure between the measured object and the reference object, the device can detect very tiny leakage through the use of differential pressure sensor with high sensitivity. During the detection, there is need to put the workpiece into the sealed capsule for pressurization or vacuumization. If there is a small leak in the workpiece, the pressure in the sealed capsule will change, thus detecting small leakages. If there is a large leak in the workpiece, the gas will fill the inner cavity of such workpiece during the air charge. At this time, the large leak can be detected by the way of pressure allocation and pressure distribution.



## 差压法检漏的优势 Advantages of differential pressure leakage detection

<b>对比</b> Comparisons	<b>绝压直压法</b> Absolute pressure & gage pressure method	<b>气泡法</b> Air bubble method	微生物浸入法 Microbial immersion method 抽真空模式的示踪气体检测 Tracegras detection vacuum mode	<b>导电率和电容 (高圧检漏)</b> Electrical conductivity and capacitance(high-voltage leak dectection) <b>激光气体顶空分析法</b> Laser-based gas headspace analysis
差压法 Differential	差压法灵敏度可达0.1Pa,比绝压直 压法提高100-200倍	差压法可定量、可重复性、 无需干燥处理	差压法 (真空衰减法) 无 细菌污染风险	差压法可适应的产品种类更丰富,对 产品内介质的导电性、成分无要求
pressure method	The sensitivity of differential pressure method can reach 0.1Pa, representing 100-200 times higher than that of absolute pressure & gage pressure method	The differential pressure method has the charac- teristics of quantifiability, repeatability and no drying treatment	No risk of bacterial contamination if differential pressure method (vacuum attenuation method) is used	Differential pressure methods is applied to more kind of products, and for the medium of product, the methods have no request of conduction of electricity and composition

# 工作流程 Workflow





# 典型应用 Typical application

### **药品:**西林瓶·安瓿瓶·药液袋/输液袋·PTP包装·气调包装·预充注射器·泡罩 包装·滴眼液容器等。

Medicine: Vial bottle, ampoule bottle, liquid medicine bag/fluid infusion bag, PTP package, MAP (modified atmosphere packaging), prefilled syringe, blister package, eye drop container, etc.

#### 食品:密封袋,塑料瓶,易拉罐等。

Food: sealed bags, plastic bottles, easy-open can, etc.





#### 检测结果管理界面——条件筛选检测结果,不能删除,可进行数据统计分析、报表输出,具有审计追踪功能。

Test result management interface——Conditional screening test results cannot be deleted. They can be used for data statistical analysis and report output. They also have auditing and traceability functions.

用户管理界面——添加、删除、修改客户权限和密码等,软件登录需要用户名和密码才能进入。

User management interface—Addition, deletion and modification of customer permissions and passwords, etc. Software login requires username and password for entry.

设备自检界面——仪器上电自检功能,进入设备维护界面可检查内部单元的工作正常情况。

Equipment self-test interface—The device is provided with POST (power on self test), and the normal operation of the internal unit can be checked after the entry of the equipment maintenance interface.

## 吹扫功能 Purge function

当包装有大漏时,包装内的液体会进入到测试腔体或管路中,导致液体汽化影响下次检测结果。对整套检测系统进行吹扫,目的是降低背景噪音,提高检测灵敏度,提高系统稳定性。

When there is a large leak in the package, the liquid inside the package will enter the test cavity or pipeline, causing liquid vaporization and affecting the next test results. Purge of the entire detection system shall be carried out in order to reduce the background noise, improve the detection sensitivity and enhance the system stability.

## 测试管路调整功能 Test pipeline adjustment function

MSP-800具有测试管路调整功能,即使应频繁更换测试条件或工件,也能使测试结果达到最优,适合实验室小批量、多品种检测。

MSP-800 has the adjustment function of test pipeline. Even if the test conditions or the workpieces are changed frequently, the test result can reach the best, which is suitable for small batch and multi-species test in the laboratory.

## 自动漏率校准功能 Function of automatic leakage rate calibration

更换一种未知的检测条件或工件种类后,仪器需要根据新条件进行漏率校准,以确保检测结果的准确性。校准过程自动进行,校准结果保存后,下次使用 相同条件时可直接检测。

After changing to an unknown test condition or workpiece type, the instrument needs to calibrate the leakage rate according to the new condition so that the accuracy of test results can be guaranteed. The calibration process shall be carried out automatically. After the calibration results are saved, direct detection is possible when the same conditions are used next time.

## 配备标准漏孔(标准阳性瓶) Provision of leak standards (Defective package)

# 规格 Specification

测定方式 Measuring method	差压式气密检漏仪 Differential pressure type air leak tester
差压传感器 Differential pressure sensor	±2kPa/2V,精度Accuracy≤±( 1%R.D. +2Pa)
差压分辨率 Differential pressure resolution	0.1Pa
直压传感器 Direct pressure sensor	精度Accuracy≤ ±0.5% F.S.
最小可检漏率 Minimum leak detection rate	1×10 <sup>-5</sup> Pa.m³/s (25°C, 入口101325Pa.abs, 出口133.322Pa.abs时,相当于孔径1µm) 1×10 <sup>-5</sup> Pa.m³/s (25°C, inlet 101325Pa.abs, outlet 133.322Pa.abs, that the equivalent of bore diameter 1µm )
单机内容积 Inside volume of single unit	≤2mL(单侧 one-side)
显示方式 Display mode	15寸触摸屏LCD显示 (24位彩色) 有效显示尺寸W304mm×D208mm 15-inch touch screen LCD display (24-bit color) Effective display size W304 mm × D208 mm
组号设定 Group number setting	任意增加产品检测数据,数据不限 Adding test data as you need without limit
温、湿度范围 Temperature and humidity range	使用:0~40 °C 储存:-5~45 °C <85% RH(无结露) Use: 0-40°C Storage: - 5-45°C <85% RH (no condensation)
电源电压 Supply voltage	AC100V~240V,50/60Hz,功率≤200W AC100V~240V,50/60Hz,power≤200W
重量 Weight	主机:约52kg 检测工装:约7kg 压力控制盒:约7kg Main machine: About 52kg Test fixture: About 7kg Pressure control box: About 7kg

# MSP-8001-23-4-5

## ①压力范围

## **Pressure range**

记号 Item	使用范围 Working range	显示范围 Display range
L	-100~200 kPa	-100∼220 kPa
M*	-100~700 kPa	-100~7700 kPa
H*	-100~1000 kPa	-100~1100 kPa

②泄漏检测范围
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Leak detection range

记号	使用范围	显示范围
Item	Working range	Display range
1	小泄漏 Small leakage	±2000Pa

#### ③自动漏率校准功能

Function of automatic leak rate calibration

	记号 Item	表示 Description
	0	无自动校准功能 No calibration function
	2	带0.1mL自动校准功能 With 0.1mL calibration function
	3	带1.0mL自动校准功能 With 1.0mL calibration function

## ④自动TANK配容功能

#### Automatic TANK matching function

记号 Item	表示 Description	
1	带0±5.0mL自动配容功能 With 0 ± 5.0mL capacity allocation function	
2	带5±5.0mL自动配容功能 With 5 ± 5.0mL capacity allocation function	
3	带10±5.0mL自动配容功能 With 10 ± 5.0mL capacity allocation function	
A	带0±5.0mL手动配容功能 With 0 ± 5.0mL manual capacity allocation function	
В	带5±5.0mL手动配容功能 With 5 ± 5.0mL manual capacity allocation function	
С	带10±5.0mL手动配容功能 With 10 ± 5.0mL manual capacity allocation function	

※ M、H型订货前请咨询 Please contact us if you order M/H-type

#### ⑤工件托盒尺寸 Dimensions of the workpiece capsule

## 记문 表示 Description Item $128mm \times 40mm \times 40mm$ 1

## 选购品(需单独购买) Options (to be purchased separately)

## 压力控制盒 PC-800- 🕕- 2 - 🕄 Pressure control box

说明

Description

-100~200 kPa

-100~700 kPa

-100~1000 kPa

①压力范围

**Pressure range** 

记문

Item

L

Μ

Н

②减压方式

记문

Item

1

**Depressurization mode** 表示

Description

Manual pressure regulation

手动调压

#### ③内置真空泵 Built-in vacuum pump

记号 Item	说明 Description
Ν	无 (需接外部真空源) None (external vacuum source required)
1	内置真空泵 Built-in vacuum pump

# 外形尺寸(单位:mm) External dimensions(Unit:mm)

## 主机 Main machine



# 压力控制盒

**Pressure control box** 

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办事处地址



主要产品

● 气密检漏仪 ● 数字压力表 ● 流量计 自动压力、流量控制器



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代理经销商

● 密封性能检测专用设备

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