

SM86 无菌检查系统 Sterility Test System







工作原理 Work Principle

SM86型无菌检查系统是基于薄膜过滤法的原理,通过定向加压作用,将液体样品加至集菌培养器内并正压过滤,过滤后冲洗滤膜除去产品的抑菌剂,然后在滤器内灌装培养基进行培养,以检验供试品是否含菌。该产品可广泛适用于无菌制剂的无菌检测,包括抗生素类及含有抑菌成分的药品、大输液、水针剂、灭菌医疗器具、无菌注射用水等。

2015年版《中国兽药典》《中国药典》无菌检查的首选方法。

SM86 Sterility test system is based on the principle of Membrane Filtration by the action of directional peristaltic pressure, filling testing sample into the closed canister and filtration by the positive pressure of the device. Rinsing membrane to remove the bacteriostatic ingredient if samples included. Appropriate medium is pumped into each canister separately to promote the growth of the captured organisms. The canisters are incubated and examined for contamination in accordance with the relevant pharmacopoeia. Many types of sterile products can be tested, includes antibiotics and drugs containing antibacterial ingredients, infusion, injection, sterilization medical equipment, sterile water for injection, etc. First method of Sterility test in Chp2015, Chinese veterinary pharmacopoeia.

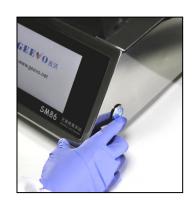
技术性能特点 Technology Characteristics

- 1. 仪器采用全不锈钢镜面外壳设计,便于表面的卫生清洁,提高仪器的使用寿命
- 2. 超大尺寸 (7 英寸) 工业级 IPS 防眩防紫外电容触摸屏,数据录入更方便,操作更灵敏
- 3. 独创培养器标签打印功能,与打印机连接,可直接将实验的相关信息打印到不干胶标签上,贴于培养器上,避免了传统在培养器上手写的方法,提高实验数据标注的标准化。打印信息有:样品名称、样品批号、操作员、实验时间及相应的厌氧菌、真菌、阳性对照等标识
- 4. 无菌检查操作管理软件有2个操作模式:可储存操作程序模式和临时操作模式。
- 5. 配有医用防水脚踏控制开关,间断运行和连续运行 2 种模式选择,方便操作,避免样品污染
- 6. 仪器启动快, 转速稳定
- 7. 排液槽的培养器托板和底槽可分离设计,并可180°旋转或台面放置。
- 8. 侧装带亮灯按钮式电源开关
- 9. 样品放置篮可同时满足样瓶放置和袋装样品钩挂
- 10. 可选择简体中文和英文操作语言
- 1. Whole mirror polished stainless steel process, easy to clean and disinfection.
- 2. 7inch capacitive touch screen, supply good user experiences for information display and input.
- 3. The unique label print function, connect with the printer, can print the relevant information of the experiment to the sticker and stick it on the canister body directly, which avoids the traditional method of hand-writing on the canister body, improves the standardization of the labeling of experimental data.
- 4. Two operation mode: Program operation and Direct operation.
- 5. Equipped with medical waterproof footswitch, intermittent operation and continuous operation of 2 modes.
- 6. Run is quickly and speed is stable.
- 7. Drain tray can be hung and lay on the table. When it is hung, more than 180 angle for choice.
- 8. Side installed with pushbutton power switch with light.
- 9. Bottle holder can meet the demand on hanging for the pouch.
- 10. English and Chinese operation language for choice









标准化简单操作 Standardize simple operation

- ◆ 可预存 20 个样品的操作 SOP, 操作过程随时查询每个样品的相关操作数据。
- ◆ 简单的无菌检查操作管理软件,操作步骤只需按屏幕提示逐步操作即可完成整个无菌检查操作过程。
- ◆ 保证不同操作人员操作过程高度的重复性。
- ◆ Accept 20samples SOP, can inquiry SOP of each sample.
- ◆ Simple sterility test management software, operation steps just follow the screen instructions to finish the whole sterility test process.
- ◆ Guarantee high repeatability for different operators.



安全方便的外接控制配合 Safe and easy external control

- ◆ 小型外接标签打印机,单线与主设备连接,轻松自动精准的标签打印。
- ◆ 脚踏开关与操作系统界面泵启停的配合使用,操作起来得心 应手。脚踏开关的间断运行模式和连续运行模式,大容量和 小容量样品都能容易控制泵的运行。
- ◆ 防水航空插头,接触性好,接□更安全。
- ◆ External min. label printer, single line connect with device, print easily and accurately.
- ◆ Footswitch works with operation system interface to control the operation mode: Intermittent operation and continuous operation. Large or small capacity samples can be controlled pump running well.
- ◆Waterproof aerial plug, good contact, more secure interface.

独创培养器标签打印功能 Unique label print function

- ◆ 原先无菌检查结束后,培养器上手写标注相关信息,标 注不规范,而且费时。
- ◆ 独创培养器标签打印功能,一键完成,打印所需标注信息分别贴到相应培养器杯壁上。
- ◆ 培养时相应培养器读取信息方便。
- ◆ As traditional method after finish sterility test, canister body will be written with information by hand.
- ◆ GEEVO unique label print function, will print the relevant information of the experiment to the sticker and stick it on the canister body directly,
- ◆ Be convenient for reading the information of canister during incubator.

合理的结构设计 Reasonable structural design

- ◆ 超大尺寸 (7 英寸) 工业级 IPS 防眩防紫外电容触 摸屏,数据录入更方便,操作更灵敏。
- ◆ 可360°旋转样品瓶悬杆配合高度可调的样品放置 篮,满足不同操作人员操作习惯需要。样品放置篮 顶部挂钩设计,方便软袋装样品的放置需求。
- ◆ 排液槽的培养器托板和底槽分离设计,更加利于排液槽的清洁和灭菌,避免灭菌死角。排液槽侧装可180°角度转动和台面放置多种角度多种放置方式,有效利于有效操作台面。
- ◆ 右侧带亮灯按钮式电源开关,醒目且便于操作。
- ◆ 机箱前部翻翘设计,避免液体前淌,保护屏幕。
- ◆Extra-large (7") industrial-grade IPS anti-glare and anti-uv capacitive touch screen, more convenient for data entry and more sensitive for operation.
- ◆Bottle holder can 360° degree swing and up & down move to choose suitable position. also meet the demand of hanging pouch.
- Drain tray can be disassemble to be drain tray container and drain tray support, is convenient for clean and disinfection, avoiding pollution. It can be hung or lay on the table. When it is hung, more than 180 degree angle for choice to meet requirement for different operation habit of operator.
- ◆Side installed with waterproof pushbutton switch with light.
- ◆Rising design on front of the device to avoid the flow of liquid and protect the screen.

技术参数 Technology Parameter

电源 Voltage	220V\110V±10%, 50/60Hz
总功率 Total power	120W
电源开关 Pushbutton power switch	防水按钮式开关,带亮灯 / Waterproof button switch with light
打印机插口 Printer inlet	5 芯防水航空插□ / 5 core waterproof aerial plug
脚踏开关插口 Footswitch inlet	3 芯防水航空插□ / 3 core waterproof aerial plug
转速范围 Rotation speed	最高转速 240 转/分钟 / Up to 240rpm
预存样品 SOP 信息 Prestore SOP information	50 ↑ pcs
显示屏 Touch screen	7 英寸高清触摸式电容屏 / 7inch high definition touch capacitive screen
操作语言 Operating language	简体中文、英文 / Chinese \ English
机箱 Pump housing	304 不锈钢镜面抛光 / 304 stainless steel mirror polished
培养器托板 Drain tray support	316L 不锈钢镜面抛光 / 316L stainless steel mirror polished
排液槽底槽 Drain tray container	聚苯砜 (PPSU)
主机总量 Weight of pump device	14.8Kg
主机尺寸 (mm) Pump device size	610×380×420 (W×D×H)
打印机尺寸 (mm) Printer device size	133×186×128 (W×D×H)
标签尺寸(mm)Print paper size	50×25 (W×L)





集菌培养器与 SM86 集菌仪配合使用。

- 1. 型号选择——根据样品包装(大输液玻璃瓶、塑料瓶、软袋、西林瓶、安瓿瓶等)、样品的性状(水剂、油性还是粉剂,无抑菌性还是抑菌性,易溶性还是难溶性等)
- 2. 根据检验需要用户可以选择两联和三联
- 3. 吸塑盒包装,有效避免培养器在运输过程中破损。
- 4. 灭菌方式: 环氧乙烷灭菌、钴60

It works together with SM86 sterility test device.

- Type choice depends on the testing sample package(LVP glass bottle, plastic bottle, soft pouch, vial and ampoule) and feature of testing sample(Water agent, oil or powder, no bacteriostasis or bacteriostasis, soluble or insoluble, etc)
- 2. Double and triple for choice
- 3. Blister box package, avoid closed canister being damaged during transportation effectively.
- 4. Sterilization mode: EO and Gamma.



培养器专用托盘 Pallet for Closed Canister

药品无菌检查中所用到集菌培养器,培养过程中需要把培养器取出培养箱进行观察记录,该托盘可以方便码放和拿取,避免翻到。

- 1. 采用 304 不锈钢材质
- 2. 托盘侧面圆角矩形开口方便手提和从培养箱中取出
- 3. 10 孔和 20 孔两种规格

PALLET-10 (10 孔) PALLET-20 (20 孔)

During handle the closed canister after the sterility test, place it on the worktable and incubator for culturing always have the trouble of overturn. And this one can solve it and be easy for operator to check.

- 1. 304 stainless steel
- 2. Rounded rectangular openings for portable, easy to take it from incubator.
- 3. Two types: Pallet-10 and pallet-20 Pallet-10 (10 holes) Pallet-20 (20holes)

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