

SHANDONG XINHUA MEDICAL INSTRUMENT CO.,LTD.

地 址: 山东省淄博高新区北辛路99号新华医疗科技园C区

电 话: 0533-3583770 传 真: 0533-3584463 技术咨询电话: 0533-3814666

邮 编: 255086

电子信箱: busi-ptdsales@shinva.com

网 址: www.shinva.net





0)+

致力于

专业化·自动化·智能化·信息化的

制药工程整体解决方案

Committed to the specialization, automation, intelligence and informatization of pharmaceutical turnkey solution

CATALOGUE

11

13

SUPER-HATED WATER STERILIZER

		21	DRY HEAT STERILIZER 干热灭菌器
		23	PHARMACEUTICAL WASHING MACHI制药用清洗机
01	STEAM STERILIZER 通用蒸汽灭菌器	25	WASHING STATION 制药用清洗站
03	RAPID COOLING STEAM STERILIZER 快速冷却灭菌器	27	RAW MATERIAL BUCKET AUTOMATIC WASHING AND STERILIZATION SY原料药桶自动清洗灭菌系统
05	BIOLOGICAL LAB STEAM STERILIZER 生物实验灭菌器	29	ENGINEERING DESIGN CENTER OF SHN 新华医疗工程设计中心
07	POWDER STEAM STERILIZER 粉类干燥灭菌器	31	WHOLE SERVICE SYSTEM 整体服务系统
09	AMPOULE STEAM STERILIZER 安瓿蒸汽灭菌器		
11	AMPOULE WATER STERILIZER		

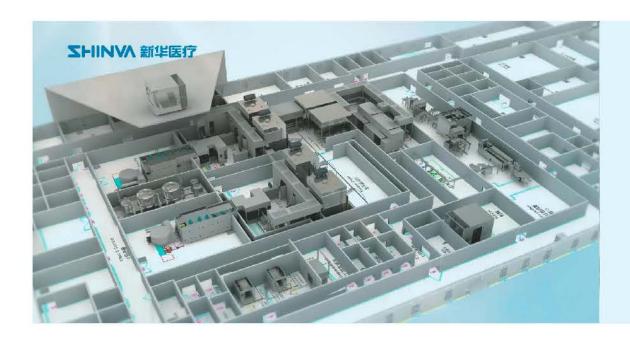
19

DYNAMIC WATER STERILIZER

AIR STEAM MIXTURE STERILIZER 通风干燥式灭菌器

动态水浴灭菌器

ABOUT US



我们已是:中国制药工程全领域极具影响力的制药装备技术供应商;

我们设立:生物制药、注射剂、固体制剂、中药制剂四个工程技术中心;

我们期望:在制药工艺、制药装备、制药工程三位一体的高度,为客户提供全方位的服务;

我们能够:为化学药、生物药、植物药的工程建设提供从概念设计、工艺试验、厂房规划、设备选型,到竣工验收、人员培训等总包服务。

We are: the most influential equipment supplier in all pharma engineering fields;

We have: 4 engineering technology centers-biopharma, injection, solid preparation, Chinese herbal preparation;

We expect: to provide client with all-round service from the height of pharma process, equipment and engineering.

We are capable: to provide turnkey service ranging from concept design, process test, plant planning, equipment selection, completion acceptance and training for engineering construction of chemical, biological and herbal mechine.

SGL series Steam Sterilizer

SGL系列 通用蒸汽灭菌器



Product Introduction

产品简介

脉动真空的工艺过程保证了空气在腔体灭菌时完全被排除,从而确保饱和蒸汽能够充满整个 腔体并且能够渗透到机器零部件和多孔产品中。

该灭菌器可广泛应用于制药生物工程、医疗卫生、实验动物等领域,对灭菌要求极高的工器 具、无菌衣、胶塞、铝盖、原辅料、过滤器、培养基等物品的灭菌处理。

Initial evacuation of the air by vacuum/steam pulse ensures thorough air removal. Saturated steam finds its way to fill the whole chamber and penetrate into porous and solid load. The sterilizer can be widely used in the fields of pharmaceutical bioengineering, health care, laboratory animals and so on. It can be used in sterilization process for tools, instruments, sterile garments, rubber stopper, aluminum cap, raw materials, filter and culture medium which have very high sterilization requirements.



Product Advantages

产品优势

全自动生产线,机器人自动焊接、自动磨光工艺;

Automatic robot welding, automatic polishing, reliable quality;

全不锈钢主体材质组合,设计使用寿命可达15年;

Stainless steel main body, design service life up to 15 years;

全新节能、降噪、无压控温排放系统,经济、安全、环保;

Brand new energy-saving, noise-reducing, non-pressure temperature control drain system is economic, safe and environmentally friendly;

温度压力全闭环PIPD控制,温度控制更均匀;

Temperature and pressure fully closed-loop PIPD control, uniform temperature control;

智能化控制系统,符合FDA审计追踪要求。

Intelligent control system that meet FDA audit trail requirements.



Product Use

产品用途

多孔负载:纺织品、滤芯、胶塞、ATF系统纤维柱等

硬质负载: 工器具、玻璃器皿、金属容器等

液体负载: 培养基等非密闭液体

Porous load: fabric, filter element, rubber stopper, fiber column of ATF system, etc.

Hard load: tools, glassware, metal containers, etc. Liquid load: non-sealed liquid such as culture medium











01 | 通用蒸汽灭菌器 STEAM STERILIZER | 02

SRC series Rapid Cooling Steam Sterilizer

SRC系列 快速冷却灭菌器



Product Introduction

产品简介

SRC系列快速冷却灭菌器配置新华独特的夹层水冷系统,可实现灭菌后的快速冷却功能。独有的专利主体结构,保证了夹套覆盖面积的同时大大降低了夹套容积,节能节水。该系列灭菌器适用于对灭菌要求极高的工器具、玻璃器皿、无菌衣、医用敷料、过滤器等物品灭菌,尤其适用于需要快速冷却的开口液体的灭菌处理。

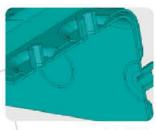
SRC Series rapid cooling sterilizer adopts SHINVA unique jacket water cooling system, achieved fast cooling performance after sterilization. The unique patent structure ensures the large jacket cover area and reduce the volume of jacket channel, to achieve energy saving and water saving purpose. This series sterilizer is suitable for the high level strictly requirements sterilization of instruments, glass ware, sterile clothing, surgical dressing, filter, especially for the liquid in opening container sterilization which needs rapid cooling.

Product Advantages

产品优势

新华专利夹套结构,节能、节水;

SHINVA patent jacket structure, energy-saving and water-saving;



夹套结构 Jacket Structure

全自动生产线,机器人自动焊接、自动磨光工艺;

Automatic robot welding, automatic polishing, reliable quality;



Temperature and pressure fully closed-loop PIPD control, uniform temperature control;

全新节能、降噪、无压控温排放系统,经济、安全、环保;

Brand new energy-saving, noise-reducing, non-pressure temperature control drain system is economic, safe and environmentally friendly;

夹套注水快速冷却系统,液体降温速度大幅缩短。

Jacket cooling system greatly shorten the cooling time of liquid cycle.

Liquid Cooling Rate

液体冷却速度对比

灭菌物品	培养皿	20L铝桶	250ml大输液	500ml大输液
Sterilization	(盛培养基)	(盛纯化水)	(开放式)	(开放式)
冷却方式 Articles	Culture Dish	^{20L Aluminum Drum}	^{250ml Large IV}	500ml Large IV
Cooling Method	(Culture Medium)	(Purified Water)	Open Type	Open Type
夹层水冷	0.54X分钟	0.7Y分钟	0.67Z分钟	0.58T分钟
Jacket Water Cooling	0.54X min	0.7Ymin	0.67Zmin	0.58Tmin
常规风冷	X分钟	Y分钟	Z分钟	T分钟
Air Cooling	Xmin	Ymin	Zmin	Tmin

说明:数据来自型号:SRCH-A-650D的不同冷却方式效果验证,冷却温度由121℃降至80℃。

Explain: Data from different cooling methods for SRCAHE-RE1D, the temperature drops from 121°C to 80°C.

Product Use

产品用途

多孔负载: 纺织品、滤芯、胶塞、ATF系统纤维柱等

硬质负载: 工器具、玻璃器皿、金属容器等

液体负载: 培养基等非密闭液体

Porous load: fabric, filter element, rubber stopper, fiber column

of ATF system, etc.

Hard load: tools, glassware, metal containers, etc.

Liquid load: non-sealed liquid such as culture medium











03 | 快速冷却灭菌器

SBE series Biological Lab Steam Sterilizer

SBE系列 生物实验灭菌器



Product Introduction

产品简介

SBE系列生物实验灭菌器按照三级生物安全要求设计,具备废气处理、废水处理与生物隔离功能,可充分保证操作人员、环境的安全。灭菌器可应用于对含有高致病性细菌病毒物品的动物尸体、生物制品、器皿、无菌衣、医用敷料、疾病材料等物品的灭菌处理。

SBE Series Biological Safe lab (BSL) sterilizer is designed according to the three levels of biosafety requirements, with waste gas treatment, waste water treatment and biological isolation function, which can ensure the safety of operators and environment. This Series sterilizer can be used to sterilize animal carcasses, biological products, vessel, sterile clothing, medical dressings, disease materials and other items containing highly pathogenic bacterial virus.

Product Advantages

产品优势



机器人自动焊接、自动磨光工艺,质量更可靠;

Automatic robot welding, automatic polishing, reliable quality;

全不锈钢主体材质组合,设计使用寿命可达15年;

Stainless steel main body, design service life up to 15 years;

全新节能、降噪、无压控温排放系统,经济、安全、环保;

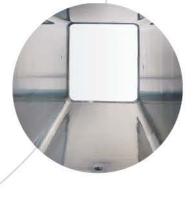
Brand new energy-saving, noise-reducing, non-pressure temperature control drain system is economic, safe and environmentally friendly;

满足三级生物安全的废气废水处理系统、生物隔离系统。

The waste gas and waste water treatment system and the biological isolation system meet the biosafety level 3.

智能化控制系统,符合FDA审计追踪要求。

Intelligent control system that meet FDA audit trail requirements.



Product Use

产品用途

带毒废弃物 Toxic waste



05 | 生物实验灭菌器 BIOLOGICAL LAB STEAM STERILIZER | 06

SMP series **Powder Steam Sterilizer**

SMP系列 粉类干燥灭菌器



产品简介

粉类干燥灭菌器的工艺过程保证了空气在腔体灭 菌时完全被排除,从而确保饱和蒸汽能够充满整 个腔体并且能够渗透到中药粉类、颗粒、药材、 片剂、制剂等中。加热与灭菌工序完全由直接注入 的洁净蒸汽完成, 并且通过夹层加热达到均匀受 热的目的。初始阶段的预热,有效解决中药粉剂 结块等现象,最后再由进一步的(简单的或多级 的)排气以及由除菌过滤后的热空气进行最后排 空来完成最终的干燥过程。

该灭菌器可广泛应用于对灭菌及干燥要求高的中 药粉末、颗粒药材等物品的灭菌及干燥处理。

The process of powder drying sterilizer ensures that the air is completely eliminated during sterilization, saturated steam enter the whole chamber and penetrate into herbal material, powder, granules, and tablets. Heating up and sterilization by directly Injected clean steam, to achieve uniform heat distribution through the jacket heating & warming. Initial preheating prevents agglomeration of herbal powder. Final drying is finished by air exhaust (through one or more times air exhaust) and by aseptic filtration hot air end exhaust out.

Technical process: dehumidification by preheating→air removal by pulse → fast heat up→sterilization→rapid drying by hot air→end.

The sterilizer can be widely used in sterilization and drying for traditional Chinese medicine powder, granule medicine and other items which have very high requirements for sterilization and drying.

Product Advantages

产品优势

配置多种干燥方式,满足中药粉不同干燥需求。

Various drying methods are configured to meet different drying requirements of TCM powder

机器人自动焊接、自动磨光工艺,质量更可靠;

Automatic robot welding, automatic polishing, reliable quality;

全新节能、降噪、无压控温排放系统,经济、安全、环保;

Brand new energy-saving, noise-reducing, non-pressure temperature control drain system is economic, safe and environmentally friendly;

多功能试验平台,可提供最佳灭菌工艺;

Multi-functional test platform to provide optimal sterilization process;

智能化控制系统,符合FDA审计追踪要求。

Intelligent control system that meet FDA audit trail requirements;

Product Use

产品用途

中药粉

TCM powder

中药材

TCM









SAS series **Ampoule Steam Sterilizer**

SAS系列 安瓿蒸汽灭菌器

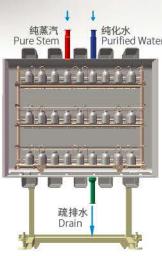


Product Introduction

产品简介

SAS安瓿蒸汽灭菌器采用高温高压的纯蒸汽作为灭菌介质,可 实现105℃~130℃温度区间的均匀灭菌,广泛用于安瓿、口服 液及小容量静脉输液等药品制剂的灭菌、检漏和清洗处理。

SAS Ampule steam sterilizer adopts hot and pressurized pure steam as the sterilizing medium to achieve the uniform sterilization between 105-130. It is widely used for sterilization, leak detection and washing of ampoules, oral liquid and small volume IV products.



Product Advantages

产品优势



标准化的管路系统,结构紧凑,便于维护;

Standardized pipeline system, compact structure, easy maintenance;



多重检漏方式,检漏更彻底;全新的清洗方式,清洗更高效节能;

Multiple leak detection methods make leak detection more thorough; brand new washing methods make washing more efficient and energy-saving;



机器人自动焊接、磨光工艺,质量更可靠;

Automatic robot welding, automatic polishing, reliable quality;



格栅分层式装载内车,温度均匀性更高;

Sterilization trolley with layered rack makes temperature distribution more uniform;

专用控制系统,控温更精确。

Dedicated control system for more accurate temperature control.

Product Use

产品用途

玻璃安瓿注射剂 西林瓶注射剂 玻璃瓶注射剂

Glass Ampoule Injection Vial Injection Glass Bottle Injection



AMPOULE STEAM STERILIZER | 10 09 | 安瓿蒸汽灭菌器

WAS series **Ampoule Water Sterilizer**

WAS系列 安瓿水浴灭菌器

WAS系列安瓿水浴灭菌器采用高温水淋浴方式对药品进行加热和灭菌, 可实现较低温度下(100℃以下)的均匀灭菌,主要用于安瓿、口服液、小 装量玻璃瓶等药品制剂的灭菌、检漏和清洗处理。

Super-heated water is used as the sterilizing medium to heat up the production by spray. Uniform sterilization at lower temperature (below 100°C) can be realized. It is mainly used for sterilzation, leak detection and washing of ampoule, oral liquid and small volume injection.



Product Use

产品用途

玻璃安瓿注射剂/塑料安瓿注射剂/口服液/西林瓶液体注射剂/大容量注射剂

Glass Ampoule Injection / Plastic Ampoule Injection / Oral Liquid / Vial Injection / Large Volume IV Injection











Product Advantages

产品优势



优化设计的喷淋系统,喷淋更均匀;

The optimized design of spray system makes spray more uniform;

机器人自动焊接、磨光工艺,质量更可靠;

Automatic robot welding, automatic polishing, reliable quality;

多重检漏方式,检漏更彻底;全新的清洗方式,清洗更高效节能;

Multiple leak detection methods make leak detection more thorough; brand new washing methods make washing more efficient and energy-saving;

格栅分层式装载内车,温度均匀性更高;

Sterilization trolley with layered rack makes temperature distribution more uniform;

专用控制系统,控温更精确。

Dedicated control system for more accurate temperature control.

WRA series **Ampoule Water** Sterilizer

WRA系列 旋转式安瓿水浴灭菌器

WRA系列旋转式安瓿水浴灭菌器主要用于安瓿瓶、口 服液瓶及小容量静脉输液瓶包装的悬浊液、乳浊液及 其它容易沉淀的或具有热敏化学特性的药液等药品的 灭菌和检漏处理。药液在灭菌全程中处于旋转状态, 不但能够使药品更均匀的接触循环水而具备优秀的温 度均匀性,而且能够防止药品在灭菌过程中发生沉淀 或者凝固等。

WRA Series Ampoule rotating type super-heated water sterilizer is mainly used for the sterilization and leak detection of ampoules, oral liquid bottles and small volume IV bottle of suspension, emulsion and other drugs that are prone to precipitation or heat sensitive chemical properties. In the process of sterilization, the liquid medicine is in a rotating state, not only make the liquid medicine more evenly contact with the circulating water, but also prevent the deposition or solidification of the liquid in the process of sterilization.





西林瓶乳浊液制剂 玻璃安瓿瓶乳浊液制剂

Emulsion Packed in Vial Emulsion Packed in Ampoule

PSM series Super-Heated Water Sterilizer

PSM系列 水浴灭菌器



Product Introduction

产品简介

采用过热水作为灭菌介质,直接喷淋产品,灭菌过程计算机自动程序控制。灭菌介质在灭菌器腔室、循环泵、换 热器、喷淋水装置内形成循环,与灭菌物品进行热交换,实现升温、灭菌、冷却等灭菌工艺过程。工业用饱和蒸 汽及冷却水均通过腔室外的热交换器加热或冷却,不与产品接触。在整个灭菌过程中通过进入腔体的可控制压力 的空气提供平衡压力,从而实现对灭菌物品的有效保护。

Superheated water, as sterilization medium, spray on products directly. The sterilization process is controlled by automatic program. Sterilization medium forms circulation in the sterilizer chamber, circulation pump, heat exchanger and spray water device, and exchanges heat with products to be sterilized for heating, sterilization and cooling. Industrial saturated steam and cooling water are heated or cooled by the heat exchanger outside the chamber without contacting with products. In the whole sterilization process, balanced pressure is realized by controlling chamber compressed air supply in order to effectively protect products.

Product Advantages

产品优势

机器人自动焊接、磨光工艺,质量更可靠;

Automatic robot welding, automatic polishing, reliable quality;

独创的节能系统,可节约能源20%以上;

The unique energy-saving system can save more than 20% of energy;

独有在线CIP清洗功能,有效防止腔体腐蚀;

Unique online CIP cleaning function can effectively prevent chamber corrosion.

自动进出料,节省人力、节约时间;

Automatic loading and unloading, saving manpower and time;

可靠的安全保护系统,如门密封压力安全保护、门关位系统保护等;

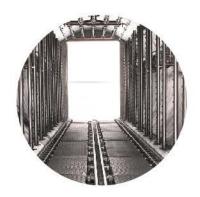
Reliable safety protection system, such as door sealing pressure safety protection, door closing system protection, etc;

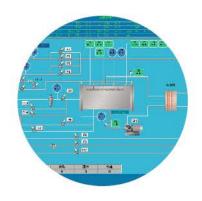
智能化控制系统,符合FDA审计追踪要求;可远程诊断、即时服务。

Intelligent control system that meet FDA audit trail requirements; remote diagnosis, real-time service;









13 | 水浴灭菌器

Product Use

产品用途









Product Category

产品分类

玻瓶大输液水浴灭菌器

Super-heated Water Sterilizer for Glass Bottle IV Solution





>适用于单室袋/多室袋/腹膜透析液/清洗液等;

- >三面喷淋,流量可调节,温度均匀性好;
- >根据客户袋型,针对性设计灭菌车。
- > It is suitable for single-chamber bag/multi-chamber bag/peritoneal dialysis/cleaning liquid, etc;
- > Three-side spray, adjustable flow rate, good temperature uniformity;
- > Customized sterilizer trolley.

塑瓶大输液水浴灭菌器

Super-heated Water Sterilizer for Plastic Bottle IV Solution





>特殊的顶部喷淋流量设计,保证喷淋均匀;

- > 匹配专用玻瓶灭菌车,可实现自动上下瓶。
- > Special top spray flow design ensures uniform spray;
- > Special glass bottle sterilization trolley, automatic bottle loading and unloading.

软袋大输液水浴灭菌器

Super-heated Water Sterilizer for Soft Bag IV Solution





>特殊的顶部喷淋流量设计,保证喷淋均匀;

- > 匹配专用塑瓶灭菌车,可实现自动上下瓶。
- > Special top spray flow design ensures uniform spray;
- > Special plastic bottle sterilization trolley, automatic bottle loading and unloading.

小容量制剂水浴灭菌器

Super-heated Water Sterilizer for Small Volume IV Solution





>特殊的顶部喷淋流量设计,保证喷淋均匀;

- > 配备专用的口服液(安瓿)灭菌车,可实现自动上下瓶。
- > Special top spray flow design ensures uniform spray;
- > Special oral liquid (ampoule) sterilization trolley, automatic bottle loading and unloading.

Energy Saving System

水浴灭菌器节能系统

减少蒸汽耗量和冷却水耗量,节约能耗;

减少升、降温时间,提高工作效率;

热水回收温度可根据瓶形实际控制情况设置;

配备正常灭菌与节能灭菌两套程序,全过程自动控制。

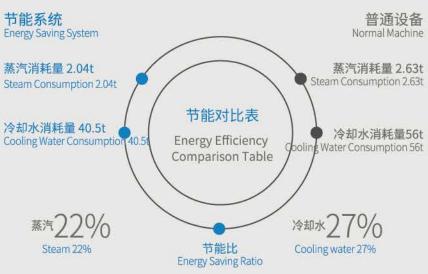
Reduce steam and cooling water consumption and save energy;

Reduce heating and cooling time, high efficiency;

Hot water recycle temperature is set according to the bottle shape actual status;

With normal sterilization cycle and energy saving cycle, whole process automatic control.





仅蒸汽一项,按照每天生产5批次,全年生产300天,可节约成本17.7万元。

As far as steam is concerned, based on the production of 5 batches per day and 300 days a year, the cost can be saved by 177,000 Yuan.

Based on PSMVP-SC-8T plastic bottle super-heated water sterilizer cycle time (sterilization temperature 121°C) *PSMVP-DC-8T 塑瓶水浴灭菌器的一个灭菌周期(121°C灭菌)为例。

MPSM/XPSM series **Dynamic Water Sterilizer**

MPSM/XPSM系列 动态水浴灭菌器



Product Advantages

产品优势



旋转/摆动架采用对称设计原理,消除了离心力,使其转动平稳;

The rotating/rocking frame adopts the symmetrical design principle to eliminate centrifugal force and make rotation stable;

支撑滚轮组件采用特殊轴承设计, 耐磨且使用寿命长;

The supporting roller assembly adopts special bearing design, which is wear-resistant and has long service life;

灭菌车采用特殊孔板结构,喷淋均匀,且保证了每个瓶子的压紧,碎瓶率低;

The sterilization trolley adopts a special perforated plate structure, and the spraying is uniform. The the compaction of each bottle is ensured, so that the bottle breaking rate is low;

采用编码器调节技术,对转速实时监测,转速异常及时报警提示;

The encoder adjustment technology is adopted to monitor the rotating speed in real time, and the abnormal rotating speed alarm is generated in time;

采用磁感应定位装置,灭菌结束后转动/摆动装置能稳定在出车位置停机。

The magnetic induction positioning device is adopted, and the rotating/rocking device can stably stop at the trolley unloading position after sterilization.



Product Introduction

产品简介

利用循环过热水作为灭菌介质,能保证输液瓶在升温过 程中实现均匀快速升降温,可实现较低温度下的均匀灭 菌,消除了蒸汽灭菌时因冷空气存在而造成的温度死 角,并可避免在灭菌后的冷却过程中由于冷却水不洁净 而造成的大输液再污染现象。药液在灭菌全程中处于运 动状态,不但能够使药品更均匀的接触循环水而具备优 秀的温度均匀性,而且能够防止药品在灭菌过程中发生 沉淀或者凝固等。灭菌过程中采用独特的压力平衡技 术,确保灭菌物品得到有效保护。

This series dynamic super-heated water sterilizer are mainly used for sterilization of suspension, emulsion and other easily precipitated or thermosensitive chemical drugs and oral liquid packaged in IV bottles. High-temperature circulating water is used as sterilization media and uniform sterilization can be realized at a low temperature (not more than 100°C). There is no problem of temperature dead leg caused by cold air in the steam sterilization and no product recontamination due to the unclean cooling water in the cooling step. The unique pressure balance technology is used in the sterilization process, and there is not explosion of bottles.

Product Use

产品用途

玻璃瓶乳浊液大输液

Emulsion Packed in Large IV Glass Bottle

软袋乳浊液大输液

Emulsion Packed in Flexible Bag

塑料瓶乳浊液大输液

Mulsion Packed in Plastic Bottle



17 | 动态水浴灭菌器 DYNAMIC WATER STERILIZER | 18

RFM series Air Steam Mixture Sterilizer

RFM系列 通风干燥式灭菌器



Product Introduction

产品简介

通过强制对流风扇和导流装置在腔体内形成灭菌介质的定向循环并能完全穿过装载的灭菌产品。通过直接进入腔体的蒸汽进行加热和灭菌。冷却通过内部高性能的热交换盘管进行。在整个灭菌过程中通过进入腔体的可控制压力的洁净空气提供平衡压力,从而实现对灭菌物品的保护措施。

工艺过程: 预热→进汽升温→灭菌→气冷→干燥→冷却→排压

The system consists of forced convection fan and air deflector. Under the strong driving of the fan and the guidance of the air deflector, the high temperature mixed sterilization medium (pure steam and clean air) in the sterilization chamber forms vortex airflow which flows evenly through the products for heating and sterilization. The temperature distribution during sterilization is within the allowable standard range. A certain amount of clean compressed air is introduced into the chamber to keep product pressure balance and prevent product damage cause by high pressure inside

Technical process:

Per-heating→ Heating→ Sterilizing→ Air cooling→ Drying→ Cooling→ Pressure relief

Product Advantages

产品优势

独特的风道循环系统设计,冷却干燥效率高;

Unique circulation system design, high cooling and drying efficiency;

独家专利的控温策略,控温更精准;

Exclusive patented temperature control strategy, more accurate temperature control;

原创发明专利,近20年的技术经验积累,拥有最丰富的工艺数据库;

Original invention patents, nearly 20 years of technical experience accumulation, the richest technological database;

机器人自动焊接、磨光工艺,质量更可靠;

Automatic robot welding, automatic polishing, reliable quality;

独创的机械密封水冷控制系统, 可靠节能;

The original mechanical seal water cooling control system is reliable and energy saving;

专用的灭菌车、灭菌盒设计,通风好,为灭菌和干燥效果提供有效保证。

The special sterilization trolley and box are designed with good ventilation to provide effective guarantee for sterilization and drying effect.







Product Use

产品用途

预充针注射器

Prefilled Syringe

粉液双室袋

Power-Liquid Double-Chamber Bag

血袋产品

Blood Bags





19 | 通风干燥式灭菌器

G series Dry Heat Sterilizer

G系列 干热灭菌器





门密封胶条采用耐高温硅橡胶双牙结构,保证密封效果,更换方便;

High temperature resistant silicone rubber door gasket, good sealing effect and easy replacement.

Product Advantages 产品优势



设备采用三维软件设计、装配; 设计温度300℃,前后门均可以做生物密封;

Three-dimensional software is adopted for design and assembly; The design temperature is 300°C, and both the front and back door can be bio-sealed.



独特的通风板和底部风道设计,温度分布更加均匀。

Unique ventilation plate and bottom air duct design make the temperature distribution more uniform.



风机变频控制;维持柜内微正压; 保证内室风速达到标准;

Frequency converter is used to control fan; Maintain a slight positive pressure in the chamber; Ensure the wind speed in the chamber reaches the standard.

Product Introduction

产品简介

在循环风机、加热管、排湿风机作用下,干燥箱迅速升温,同时洁净干燥空气通过高温高效过滤器进入箱体,吸收物料表面的水分,进入循环通道蒸发排出,干燥空气在风机作用下定向循环流动。随着水蒸气逐渐减少,同时间隙性补充新鲜过滤空气,箱体内成微正压状态,灭菌室温度达到设定值,在设定温度下保温循环,实现对灭菌物品的灭菌。

With the help of circulation fan, the dry heat air flows into chamber by way of high temperature resistant HEPA and forms uniform air flow. The dry air flows in a directional circulation, removes moisture on the surface of the articles, and then comes out of chamber. With the gradual decrease of water vapor and intermittent fresh entering, the chamber presents positive pressure state. After sterilizing stage is ended, fresh air (or cooling water) entering valve is open for cooling. When temperature drops to the set value, automatic valves close, and sound and light alarm is generated for indicating to open door.

Product Use 产品用途



玻璃瓶 (空瓶) Glass Bottles(empty)



原料药筒 API Barrels



设备零件 Equipment Parts



西林瓶(空瓶) Vials (empty)



金属容器 Metal Containers

21 | 干热灭菌器 DRY HEAT STERILIZER | 22

YQG-V series **Pharmaceutical Washing Machine**

YQG-V系列 制药用清洗机

YQG-V系列制药器具清洗机是我公司根据国内外用户 对清洗的最新要求研发生产的清洗设备,能够完成对 物品的预洗、清洗、漂洗和干燥,实现了可重现的 "能被记录和验证"的清洗,完全符合新版GMP美 国FDA和欧盟cGMP规范的要求。该清洗机具有容积 大、清洗彻底、自动化程度高的特点,各项技术指标 均能达到国际先进水平。同时设备可以配置整套符合 FDA要求的文件体系,是国内制药厂家的首选设备。

YQG-V series pharmaceutical washing machine is designed according to GMP requirements. It can processing the material pre-washing, washing, rinse and drying, that achieve reproducible "Can be recorded and verified" washing cycle to full meet China GMP, EU cGMP and USA FDA requirements. This washing machine is with the advantage of large volume, washing thoroughness, high automatic level. Each standard is high and same as the worldwide market. Also the machine can provide whole FDA approved documents that is the best choose for the pharmaceutical company.



灌装器具: 灌装泵、灌装针、硅胶管、分液器、料斗、套筒 过滤器滤壳等

生产器具:不锈钢桶、PP桶、勺子、搅拌棒、镊子、剪刀、

试验器皿: 烧杯、蓝盖瓶、量筒、三角瓶、试管、容量瓶等

Filling equipment: filling pump, filling needle, silicone tube, liquid dispenser, hopper, filter housing, etc. Production equipment: stainless steel barrel, PP barrel, spoon, stirring rod, tweezers, scissors, clamp, etc. Laboratory glassware: beaker, blue cap bottle, measuring cylinder, conical flask, test tube, volumetric flask, etc.

Product Advantages

产品优势





内室镜面处理,圆弧过渡, 无死角,易清洁。

Chamber mirror finish, round corner transition, no dead leg, easy cleaning.



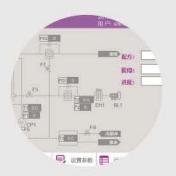
升降门结构设计,设备紧 凑,节省外部空间。

Vertical sliding door, compact design.



配置高效喷淋系统和管路设 计,节省能源,提高效率。

Door interlock function enables strict isolation of loading /unloading area and prevents cross contamination.



自动程序控制,实现"可记录、 可验证、可追溯"的清洗过程。

Automatic program control enables "recordable, verifiable and traceable" washing process.



建立清洗物品数据库, 规范 工位设计, 为客户提供定制 化和标准化清洗架。

Establish a database of items to be washed, standardize the design of work stations, and provide customized and standardized washing racks for users.

23 | 制药用清洗机 PHARMACEUTICAL WASHING MACHINE | 24

YQG-M series Washing Station

YQG-M系列 清洗站



Product Introduction

产品简介

YQG-M系列清洗站是根据用户特殊清洗需求研发的、适用于大型物品(如:料斗)或大批量物品清洗的一类设备,可实现预洗、清洗、漂洗和热风干燥等预设程序,自动化程度高,清洗彻底无死角,实现"可验证、可记录、可追溯"的清洗过程。目前,该类产品已广泛应用于生物制剂、固体制剂等多个场合。产品种类丰富,并可配套满足FDA、欧盟cGMP、国内GMP认证要求的文件体系。

YQG-M series washing station is developed according to GMP requirments and is suitable for washing large articles (such as hoppers) or large quantities of articles. It can realize preset program including pre-washing, washing, rinsing and hot air drying. It features high degree of automation, complete washing without dead corners, and "recordable, verifiable and traceable" washing process. At present, it have been widely used in biological preparations, solid preparations, etc. Documentation that meets FDA, EU cGMP and domestic GMP certification requirements can be provided.





配置升降喷淋系统,喷淋球精准定位,实现不同规格料斗、罐体的清洗;

The lifting spray system is provided and the spray ball is accurately positioned. The washing of the hopper and the tank body with different specifications can be realized;

配置卧式或立式大风量干燥进风单元,提高干燥速率,缩短流程时间;

The horizontal or vertical large air volume drying air inlet unit is provided to improve the drying rate and shorten the flow time;

采用高压清洗模式,有效节省能源,提高生产效率;

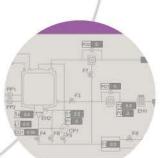
High-pressure washing mode can effectively save energy and improve production efficiency;

标准化泵站和高效喷淋系统设计,实现无死角清洗;

Standardized pump station and efficient spray system design. The washing has no dead leg;

自动程序控制,实现"可记录、可验证、可追溯"的清洗过程。

Automatic program control enables "recordable, verifiable and traceable" washing process.



La same E

Product Use

产品用途

生物制药: 蛋盘/蛋车/冻干盘; Bi

原料药: 铝听

固体制剂: 料斗/移动罐

Biopharmaceuticals: egg tray, egg trolley, freeze-drying tray

API: aluminum barrel

Solid preparation: hopper, movable tank









25 | 制药用清洗站 WASHING STATION | 26





Automatic Washing Process

全自动清洗

连续式清洗及自动隔断技术, "两水两气"四工位清洗工艺,保证清洗速度 及清洗效果。

Continuous washing and automatic isolation technology, two-water two-air total 4 washing station, to ensure washing speed and washing efficiency.



Automatic Loading and Unloading Process

全自动装卸

三坐标搬运机械手,实现A级层流下铝桶的自动无人化转运。

Three-coordinate handling manipulator realizes automatic transfer of aluminum barrel under A-level laminar flow.



Automatic Sterilization Process

全自动湿热灭菌

采用清洗加湿热灭菌去热原技术,保证灭菌效果。

Cleaning and moist heat sterilization and depyrogenation technology are used to ensure the sterilization effect.



Automatic Cap Insertion

内盖自动加盖

独创内盖自动加盖,精确实现铝盖的抓取及加盖的自动化。

Unique automatic insertion of the inner cap, automatic aluminum cap grasping

Dynamic Laminar Flow Sterilization And Drying Machine

动态层流灭菌干燥一体机

动态层流灭菌干燥一体机是专门针对中药浸膏开发设计的 一款革新性干燥设备;特别适合于温度50℃~80℃中药浸 膏的干燥,具有干燥效率高,能耗低,可在线灭菌,在线 清洗,解决了目前中药制药装备存在的能耗高效率低、与 药品生产实际工艺脱节等问题,为更新换代产品。

Dynamic laminar flow sterilization and drying machine is mainly designed for Chinese medicine extract drying machine; especially suitable for 50%~80% Chinese medicine extract drying, with high effective drying, low consumption, with capacity for SIP and CIP. It can solve the problem for low consumption effectivity and seperation for medicine real technology for product renew.



Sterile Inspection Isolator

无菌检查隔离器

SHINVA的PI-AU系列无菌检查隔离器专门为QC等执行无菌检 查工作而设计,可有效地避免检查结果的假阳性。

- ▶ 采用密闭式结构,可安装在D级以上环境,内部层流净化, 洁净等级为A级;
- ▶ 传递舱+工作舱分段结构,可根据工作量及工艺自由组合;
- ▶配备VHP灭菌系统,自动在线灭菌;
- ▶ 人机工程学设计,手套操作高度依照人员和工艺特殊设计;
- ▶ 满足GMP要求的审计追踪功能。



SHINVA PI-AU series sterile inspection isolator is special designed for sterile inspection working, which can effectively avoid false positives of inspection results

- It adopts sealed structure, which can be installed in the area higher than class D, internal laminar flow cleanness is class A;
- Passing chamber+ working chamber with different parts, which can be freely combined according to the workload and
- It is equipped with VHP sterilization system and automatic SIP system;
- Ergonomic design, glove operating height according to personnel and process specific design;



Engineering Design Center Of Shnva

新华医疗工程设计中心

作为国内领先的制药工程整体解决方案服务商,新华医疗可以为用户提供从初期概念设计到项目整体(工艺装备及工程实施)的数据化交付。

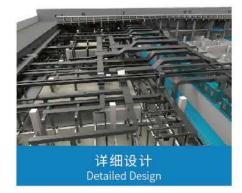
我们与西门子共同联合在生物制药行业中首次引入COMOS(工厂工程设计软件)。从设计、数字化移交到运维都在一个工程数据平台上进行,符合未来工业4.0的高标准要求。

As a leading pharmaceutical engineering solutions service provider in China, Shinva can provide service from initial concept design to the whole project (Process equipment and engineering implementation) data delivery.

We cooperated with Siemens and first introduced COMOS (Plant engineering design software) in biopharmaceutical industry. From design and digital handover to operation and maintenance, it is carried out on one engineering data platform, which meets the high standard of future industry 4.0.







Engineering Service Center Of Shinva

新华医疗工程服务中心

山东新华医疗器械股份有限公司工程服务中心,是山东新华医疗器械股份有限公司的全资子公司,公司隶属于山东新华医疗器械股份有限公司制药科技集团。工程服务中心致力安装调试、验证、设备改造、电气自动化、配件、年保设备维修和整体工程项目实施等一条龙服务,为药企的安全稳定生产保驾护航。

Engineering Service Centre of Shinva is a wholly-owned subsidiary of Shinva; the company belongs to Pharma-Tech Group of Shinva. Engineering Service Centre dedicates to installation and commissioning, validation, equipment modification, electric automatization, spare parts, annual equipment maintenance and integrated project implementation and other services, and guarantees the safe and stable production of pharmaceutical enterprises.



Business Scope Of Engineering Service Center

工程服务中心业务



验证服务整体方案 Whole Project Validation Service

29 | 新华医疗工程设计中心 ENGINEERING DESIGN CENTER OF SHNVA | 30

Life Science Industry Integration, Automation, Informationization

生命科学产业一体化、自动化、信息化

Utilities

公用工程

洁净空调控制系统 Clean conditioning system

环境监测系统 Environmental monitoring system

纯化水、注射用水系统 PW/WFI system

弱电系统集成 Weak electricity integration

能源系统 Energy system

生产设备控制系统升级 Control system updating of production equipment

生产智能信息展示系统 Display system of intelligent production information

Automation of Engineering Process

工艺过程自动化

制剂过程控制系统 Control system for drug preparations production

Control system for API production 原料药过程控制系统

生物制药过程控制系统 Control system for biological pharmaceutics production

固体制剂过程控制系统 Control system for solid preparations production 中药过程控制系统 Control system for herbal medicine production

Plant Information System 工厂信息系统

数据采集与监视控制系统 SCADA

制造执行系统 MES

信息显示系统 IDS

智能仓储管理系统 WMS

计算机化系统验证 CSV









新华医疗制药行业自动化、信息化整体解决方案 制药工程、信息工程、自动化控制、弱电系统工程

Pharmaceutical engineering, information engineering, automation engineering, weak electricity system

公用工程自动化

新华医疗提供符合GMP、FDA、EMA规范的"一站式"公用工程控制系统。通过先进的、完善的 控制方案,降低能源消耗,保障洁净室环境,减少设备故障,降低维护及运营成本。

"One-station" type utilities control system compliant with GMP, FDA and EMA can reduce energy consumption, guarantee clean room environment, lower equipment failure and maintenance cost.

工艺过程自动化

新华医疗提供符合GMP、FDA、EMA规范的"一站式"工艺过程自动化控制系统解决方案。通过 精确的、优化的控制方案保证产品质量,提高生产效率,降低生产成本,保证生产安全。

The integration solution for engineering process automation covering main process and supporting process can greatly guarantee product quality, raise production efficiency, reduce cost and ensure production safety.

工厂信息系统

新华医疗提供符合GMP、FDA、EMA规范的"一站式"工厂信息化控制系统解决方案。通过及时, 准确,全面的信息系统,提高生产协作化水平,改进生产流程,追溯事故问题,方便企业管理。 GMP, FDA, EMA compliant factory informatization solution provide quick, accurate and complete information system to improve production harmonization and process, track accident and problems and facilitate enterprise management.



31 | 生命科学产业一体化、自动化、信息化