山东精鹰机械制造有限公司

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SHANDONG **EAGLE MACHINERY** CO.,LTD

山东精鹰





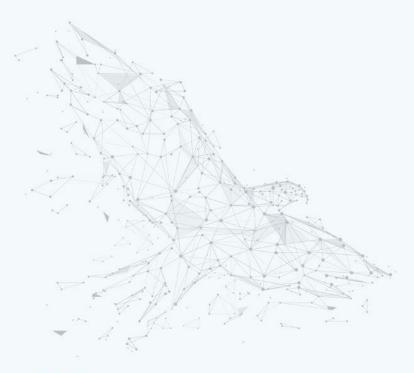
诚信立命 科技仁心

助力人类健康事业发展

Honesty and technology benevolence Promoting the development of human health







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SERVICE BRAND

打造具有国际影响力的 制药用水系统提供商

Creating a Chinese Pharmaceutical Purified
Water System Supplier
with International Influence







Shandong Eagle Machinery Co.,Ltd 山东精應机械制造有限公司



CHAIRMAN SPEECH

董事长

致辞

Shandong Eagle Machinery Co., Ltd originates from the former state-owned Weifang Medical Appliances Factory established in 1958. Striving for 60 years, WEMAC people unswervingly focus on the pharmaceutical and health industry. Adhering to the business philosophy of "Cherishing Life, Noble Responsibilities", WEMAC has been in the forefront of China's pharmaceutical water treatment industry, and has developed into an influential domestic service provider in pharmaceutical water treatment field.

WEMAC people have a long journey through trials and hardships. They are witnesses, builders and participants in China's pharmaceutical water treatment field. They are constantly innovating, closely focusing on the individual needs of customers, and continuously improving product quality and service levels.

Looking back at the long journey of the trials and hardships, WEMAC people are full of gratitude. Grateful for the prosperity of our great motherland, which has created the historical opportunity for WEMAC to flourish; grateful to every new and old customer for their trust and accompany, which illuminates the road with trials and hardships of WEMAC; grateful to every WEMAC person for their hard work and unremitting efforts, condensed to become the power of WEMAC to pursue its dreams; We are grateful to the leaders, guiders and peers who accompany and care about the development of WEMAC, which urges WEMAC to unswervingly ride the wind and waves and move forward with down-to-earth inspiration.

WEMAC has drawn up a new strategic blueprint in 2022. WEMAC people will regroup and set off again, working hard and striving to build as a world-renowned comprehensive service provider of pharmaceutical water systems.

The road will be long and full of hazards, but if we march forward, we shall reach our destination and the future can be expected.

WEMAC will join hands with all walks of life to build an ecological chain of pharmaceutical water treatment equipment services.

Let's go to the future together!

Chairman: Lizhonglin



山东精鹰机械制造有限公司源于1958年成立的潍坊医疗器械厂, 栉风沐雨六十载, 山东精鹰人矢志不渝、心 无旁骛聚焦医药健康大产业。山东精鹰秉承"关夏生命、责任至上的"理念, 一直走在中国制药用水装备领 域的前沿, 发展成为了国内具有重要影响力的医药制水装备服务商。

精鹰人,风雨兼程、征途漫漫,是我国制药用水装备市场的见证者、建设者和参与者,不断创新,紧密围绕客 户个性化需求,不断提升产品质量和服务水平。

回望單路蓋缕、风雨兼程的漫漫征程,精鷹人满怀感恩。感恩伟大祖国的富强,造就了山东精鹰蓬勃发展的 历史机遇; 感恩每一位新老客户的信任与陪伴,照亮了山东精鹰风雨兼程的道路; 感恩每一名精鹰人的辛苦 付出和不懈努力,凝聚成为山东精鹰逐梦前行的力量; 感恩陪伴和关心山东精鹰发展的领路人、引路人、同 行人,惟发出山东精鹰笃定不移乘风破浪、脚窗实地励志前行的不懈动力。

2022年,山东精鹰已绘就新的战略蓝图。精鹰人将重整行装再出发,踔厉奋发,致力于打造全球知名的制药 用水系统综合服务商。

道阻且长,行则将至,行而不辍,未来可期! 山东精鹰将携手各界打造医药制水装备服务生态链。 让我们一起向未来!

李老林

0) шепяс



山东精鹰 企业简介

山东精鹰机械制造有限公司坐落于美丽的世界风筝之都一潍坊。公司源于1958年成立的潍坊医疗器械厂,是一家集纯化水设备、注射用水设备、储存与分配系统、制药用蒸汽系统等制药用水设备的研发生产销售于一体的高新技术企业,客户遍布全国及20多个国家和地区。

公司科研实力維厚,拥有一支涵盖机械设计及其自动化、电气工程、材料加工工程、控制科学与工程、环境科学与工程、医用电子技术及设备、力学等十余个专业的高素质研发团队,可为项目咨询、项目设计、生产加工、安装调试、现场验证等提供全链条规范化服务。公司与山东大学、山东科技大学等高校、科研院所建立了紧密的产学研合作关系,致力于为制药、电子、食品等行业的广大客户提供具有可持续创新性的更加优质的制药用水系统新产品。

公司具有特种设备许可证(第一、二类中低压容器制造),拥有各种类型的数控加工中心、产品测试中心等先进的加工及检验检测设备和 科学的质量管理体系,为工期可靠性、质量可靠性提供了基础保障。

山东精鷹以自强不息之精神,以厚德载物之胸怀热烈欢迎国内外客商垂询指导、合作共赢。

SHANDONG EAGLE INTRODUCTION

Shandong Eagle Machinery Co., Ltd, is located in the beautiful international kite capital—Weifang. Originated from the former state -owned Weifang Medical Appliances Factory established in 1958, WEMAC is a high-tech enterprise integrating R&D, production and sales of pharmaceutical Purified water generation system, Multi effect water distiller, Pure steam generator, Storage and Distribution system. WEMAC enjoys a high reputation in domestic China and aboard, customers covering more than 20 countries and regions.

WEMAC has its own high-quality R&D team covers over 10 professional majors, including Mechanical Design and Automation, Electrical Engineering, Material Processing Engineering, Control Science and Engineering, Environmental Science and Engineering, Medical Electronic Technology and Equipment and Mechanics, Full-chain standardized services can be provided for Project consultation, Project design, Production and Processing, Installation and Commissioning, and On-site Validation. WEMAC has established a close industry-university-research cooperation relationships with Shandong University, Shandong University of Science and Technology and other universities and research institutes. Committed to providing sustainable and innovative higher-quality pharmaceutical water treatment systems for customers in pharmaceutical, electronics, food and other industries.

With special equipment license (Type I & Type II medium and low pressure vessel manufacturing), and various CNC machining centers, product testing centers and other advanced processing and testing equipment, as well as scientific quality management system, we provide customers with guaranteed reliability and quality of construction.





ENTERPRISE FACTORY

PRODUCTION BASE

生产基地







1 山东精鹰

Creating Water-equipment base for pharmaceutical, electronics and food industries.



SHANDONG EAGLE MACHINERY CO.,LTD





BUSINESS

PHILOSOPHY

经营理念



品牌 使命 生命科技、绿色未来,为环保事业不懈努力 以持续创新为客户创造卓越价值

Life science and technology, green future, unremitting efforts for environmental Protection Create outstanding value for customers with continuous innovation



实施人才经营战略 助推企业 创新发展

Innovative and pragmatic, united and forge ahead, people use their talents and have both ability and political integrity



员工定期专业培训,增强员工劳动技能和敬业精神,树立匠心精神与高品质服务理念。 公司各类技术工程师与专业售后服务人员,遍布全国各地,竭诚为您服务。

Regular professional training for employees to enhance their labor skills and professionalism, and establish the spirit of ingenuity and high-quality service concept. The company's various technical engineers and professional after-sales service personnel, all over the country, dedicated to your service.









一份份的荣誉是社会与客户对我公司诚信经营、真诚服务的肯定,更是对未来我们工作的肯定。 它不仅仅是一份荣誉,更是一份责任鞭策。

We take honors from the recognition from our customers and the society, which will make us to step further.













制药用水系统

PHARMACEUTICAL WATER SYSTEM



PURIFIED WATER GENERATION AND STORAGE SYSTEM

纯化水制备与储存系统



山东精鹰根据原水水质报告和出水水质要求及客户的实际需求定制最优化设计,也可选用山东精鹰标准化设计。 出水水质按系统配置的不同均可满足中国药典(CP2020)、美国药典(USP43)、欧洲药典(EP10)对纯化 水或高纯水的规范要求。

Shandong Jingying customized optimization design according to the raw water quality report and effluent quality requirements and the actual needs of customers, and can also choose the standardized design of Shandong Jingying.

The effluent quality can meet the requirements of Chinese Pharmacopoeia (cp2020), United States Pharmacopoeia (usp43) and European Pharmacopoeia (EP10) for purified water or high purity water according to different system configurations.

FEATURE 产品特点

- 1、模块化设计,结构紧凑,布局美观,方便操作和维护。
- 2、预处理双软化器利用阀门组可实现串联运行,交替再生。每台软水器均具有100%的供水能力。软化器运行、反洗、吸盐、再生、正洗等全过程采用 全自动程序化控制。
- 3、原水泵及一、二级高压泵均采用变频控制,既可实现过滤器及软化器各种运行状态下不同的压力控制,又可实现系统待机时机内产水低速小循环, 大大减少微生物滋生的机率并有效节能。
- 4、系统终端产水采用双路供水单路循环模式,即产水合格时产品水通过两条管线进入纯化水储罐。产水不合格时产水通过两条管线循环后流回中间水 储罐。纯化水储罐水满时,亦自动切换至循环管路运行,有效地避免了空管的存在,并保证没有死水存在。
- 5、管路尽可能采用不锈钢管直接拉伸弯管,避免焊接。管路与配件焊件,尽可能使用氩气保护自动焊接(单面焊双面成型工艺), 保证焊接质量, 焊后电化学抛光。
- 6、提供内窥镜检查照片、焊点图、压力测试及酸 洗钝化报告及系统设计文件等验证资料。
- 7、控制系统采用HMI+PLC全自动控制,操作界面 简便。可提供各种通讯模式。控制系统权限级 数:至少可设置三级权限。
- 8、在线监控电导率、温度和流量等参数。记录仪 即可选择无纸记录仪也可选择有纸记录仪,对 关键参数进行记录和打印。
- 9、控制系统可选配电子签名、电子记录,使系统 控制具有审计追踪功能,并满足GAMP 5要求 及符合21 CFR PART 11要求。









- 1. Modular design, compact structure, beautiful layout, convenient operation and maintenance.
- 2. The pretreatment double softener can realize series operation and alternate regeneration by using valve group. Each water softener has 100% water supply capacity. The whole process of softener operation, backwashing, salt absorption, regeneration and washing is fully automatic and programmed.
- 3. Frequency conversion control is adopted for raw water pump and primary and secondary high-pressure pumps, which can not only realize different pressure control of filter and softener under various operating conditions, but also realize low-speed and small circulation of produced water in system standby time, greatly reducing the probability of microbial breeding and effectively saving energy.
- 4. The terminal water production of the system adopts a dual-channel water supply and single-channel circulation mode, that is, when the product water is qualified. it enters the purified water storage tank through two pipelines. While when the product water is unqualified, the product water circulates through the two pipelines and then flows back to the middle water storage tank. When the purified water storage tank is full, it will automatically switch to the circulation pipeline operation, which effectively avoids the existence of empty pipes and ensures that there is no dead water.
- 5. As far as possible, use stainless steel pipes to directly stretch the elbow to avoid welding seam. Welding parts of pipelines and accessories should be automatically welded with argon protection(single-side welding and double-side forming process) to ensure welding quality, and electrochemical polishing after welding.
- 6. Provide endoscopy photos, solder joint diagram, pressure test and pickling passivation report, system design documents and other verification data.
- 7. The control system adopts HMI+PLC fully automatic control, and the operation interface is simple. Various communication modes are available. Control system authority levels; at least three levels of authority can be set.
- 8. Online monitoring of parameters such as conductivity, temperature and flow. The recorder can choose a paperless recorder or a paper recorder to record and
- 9. The control system can be optionally equipped with electronic signatures and electronic records, so that the system control has an audit trail function, and meets the requirements of GAMP 5 and 21 CFR PART 11.







WATER FOR INJECTION GENERATION AND STORAGE SYSTEM

注射用水制备与储存系统



山东精鹰LDS系列列管式多效蒸馏水机是一种以纯化水为原料水,用工业蒸汽加热制取注射用水的设备。 LDS多效蒸馏水机生产的注射用水满足中国药典(CP2020)、美国药典(USP43)、欧洲药典(EP10) 对注射用水的规范要求。

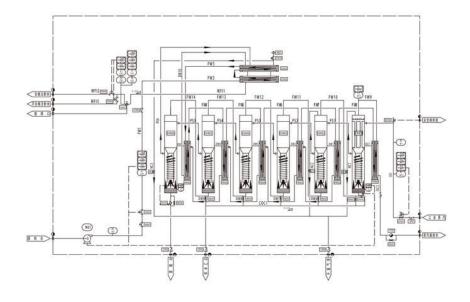
WEMAC LDS series Multi effect water distiller is a kind of water for injection generation equipment using purified water as raw water, and heated by industrial steam.

The water for injection produced by LDS series Multi effect water distiller meets the requirements of WFI in Chinese Pharmacopoeia (Cp2020), United States Pharmacopoeia (USP43) and European Pharmacopoeia (Ep10).

PRINCIPLE 工作原理

合格的原料水由多级泵增压后进入冷凝器,再依次进入各效预热器(原料水在冷凝器被二次蒸汽、蒸馏水加热,进入以后各效预热器被二次蒸汽的凝结 水加热,在一效预热器被工业蒸汽凝结水加热),然后进入一效蒸发器经料水分配器喷射在加热管内壁,使料水在管壁成膜状流动,被工业蒸汽加热气 化。产生的夹带水滴的二次蒸汽,从蒸发室下端进入汽水分离装置,被分离的纯蒸汽进入下一效作为加热蒸汽,未被蒸发的原料水进入下一效,重复上 还过程。末效产生的纯蒸汽进入冷凝器同来自除一效之外的各效的冷凝水汇合冷却,经排除不凝性气体后(根据机型的不同,在蒸发器上也可设有此种 不凝气体连续排放装置),成为注射用水。出口一般经过电导率的在线检测,合格的蒸馏水作为注射用水输出,不合格的蒸馏水将被排放。

Qualified raw water is pressurized by a multi-stage pump and then enters the condenser, and then enters each effect preheater in turn (the raw water is heated by secondary steam and distilled water in the condenser, and after entering each effect preheater is heated by condensed water of secondary steam, which will be heated by industrial steam condensed water in the first-effect preheater). Then it enters the first-effect evaporator and sprayed on the inner wall of the heating tube through the material water distributor, so that the material water flows in a film status on the tube wall, and is heated and vaporized by the industrial steam. The generated secondary steam with water droplets enters the steam-water separator from the lower end of the evaporation chamber, the separated pure steam enters the next effect as heating steam, and the unevaporated raw water enters the next effect, and the above process is repeated. The pure steam generated by the final effect enters the condenser and is cooled by condensing water from each effect except the first effect. After removing the non-condensable gas (depending on the model, the evaporator may also be equipped with such a continuous discharge device of non-condensable gas). Condensed gas becomes water for injection. The outlet generally undergoes online conductivity testing, qualified distilled water is output as water for injection, and unqualified distilled water will be discharged.









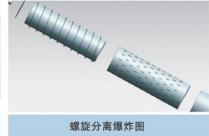


FEATURE 产品特点

- 1、结构形式:外置预热器、冷凝器和一效蒸发器均为双管板设计,采用内管板胀接外焊接工艺,避免交叉污染。
- 2、分离装置:具有降膜蒸发、重力分离及螺旋绕流三级分离。
- 3、材料材质:与原料水、注射用水、二次纯蒸汽接触的部分全部采用SS316L。
- 4、保温隔热:蒸发器、预热器、冷凝器均采用硅酸铝针刺毯,具有延伸性好,质量轻,隔热性极佳,有较强的稳定性。
- 5、表面处理: 内外表面电化学抛光,有效保证不锈钢表面的光洁度。
- 6、节能降耗:多效蒸馏水机由于二次蒸汽在各效中逐级利用,因此对工业蒸汽的利用率很高,具有明显的节能效果。随着蒸发器效数的增多,这种 节能的效果更加明显。同时冷却水的用量也随效数的增加大幅减少。本公司生产的五效蒸馏水机使用少量冷却水,六效蒸馏水机不用冷却水。
- 7、管路尽可能采用不锈钢管直接拉伸弯管,避免焊接。管路与配件焊件,尽可能使用氮气保护自动焊接(单面焊双面成型工艺),保证焊接质量,焊后电化学镜光。
- 8、提供内窥镜检查照片、焊点图、压力测试及酸洗钝化报告及系统设计文件等验证资料。
- 9、控制系统采用HMI+PLC全自动控制,操作界面简便。可提供各种通讯模式。控制系统权限级数:至少可设置三级权限。
- 10、在线监控电导率、温度和流量等参数。记录仪即可选择无纸记录仪也可选择有纸记录仪,对关键参数进行记录和打印。
- 11、控制系统可选配电子签名、电子记录,使系统控制具有审计追踪功能,并满足GAMP 5要求及符合21 CFR PART 11要求。
- Structure: The external preheater, condenser and first-effect evaporator are all designed with double tube sheets, and the inner tube sheet is expanded and welded externally to avoid cross contamination.
- 2. Separation device: three-stage separation with falling film evaporation, gravity separation and spiral flow.
- 3. Material: all parts in contact with raw water, water for injection and secondary pure steam are made of SS316L.
- 4. Thermal preservation and insulation: the evaporator, preheater, and condenser all use aluminum silicate needle punched blanket, which has good extensibility, light weight, excellent heat insulation and strong stability.
- $5. \, Surface \, treatment: \, The \, internal \, and \, external \, surfaces \, are \, electrochemically \, polished \, to \, effectively \, ensure \, the \, smoothness \, of \, the \, stainless \, steel \, surface.$
- 6. Energy saving and consumption reduction: Since the secondary steam is used step by step in each effect,
- the multi-effect water distiller has a high utilization rate of industrial steam and has obvious energy saving effects.
- With the increase in the number of evaporators, this energy saving effect becomes more obvious. At the same time,
- the amount of cooling water is also greatly reduced as the effect number increases.
- The five-effect distiller produced by our company uses a small amount of cooling water, and the six-effect distiller does not require cooling water.
- 7. Use stainless steel pipes as far as possible to directly stretch the elbow to avoid welding. Welding parts of pipelines and accessories should be automatically welded with argon protection (single-side welding and double-side forming process) to ensure welding quality, and electrochemical polishing after welding.
- Provide verification materials such as endoscopic inspection photos, solder joint diagrams, pressure test and pickling passivation reports, and system design documents.
- The control system adopts HMI+PLC fully automatic control, and the operation interface is simple. Various communication modes are available.
 Control system authority levels: at least three levels of authority can be set.
- $10. \, \hbox{Online monitoring of parameters such as conductivity, temperature and flow}.$
- $The \, recorder \, can \, choose \, a \, paperless \, recorder \, or \, a \, paper \, recorder \, to \, record \, and \, print \, key \, parameters.$
- 11. The control system can be equipped with electronic signatures and electronic records to make the system control with audit trail function, and meet the requirements of GAMP 5 and 21 CFR PART 11.



螺旋安装示意



PARAMETER 参数表

工作压力0.3MPa的情况下 industrial steam pressure 0.3MPa

	产量 Capacity (L/h)	工业蒸汽耗量 Industrial steam consumption (L/h)	原料水耗量 Feed water consumption (L/h)	冷却水耗量 Cooling water consumption (L/h)	外形尺寸 Dimensions (mm)
LDS100-4	≥100	30	110	80	1080×585×2800
LDS300-5	≥300	80	330	170	1760×755×3000
LDS500-5	≥500	115	550	190	2000×805×3500
LDS1000-5	≥1000	250	1100	350	2300×1000×4000
LDS1000-6	≥1000	210	1100	0	2930×1000×4000
LDS2000-6	≥2000	440	2200	0	3650×1200×4100
LDS3000-6	≥3000	670	3300	0	3800×1200×4200
LDS4000-6	≥4000	900	4400	0	4300×1250×4500
LDS5000-6	≥5000	1130	5500	0	4600×1400×4600
LDS6000-6	≥6000	1350	6600	0	4600×1400×4900



PURE STEAM GENERATOR

纯蒸汽发生器



山东精鹰CZQ系列纯蒸汽发生器是一种以纯化水为原料水,用工业蒸汽加热 制取洁净纯蒸汽的设备。此系列设备可用于制药设备和各种工艺生产线(管道、 储罐等)的灭菌与消毒。其生产的纯蒸汽的冷凝水满足中国药典 (Cp2020)、 美国药典 (USP43)、欧洲药典 (EP10) 对注射用水的规范要求。

CZO series Pure steam generator of WEMAC is a kind of equipment that adopts purified water as raw material water and heated by industrial steam to produce clean pure steam. This series of equipment can be used for sterilization and disinfection of pharmaceutical equipment and various process production lines (pipelines, storage tanks, etc.). The pure steam condensed water produced meets the requirements of the Chinese Pharmacopoeia (CP2020), United States Pharmacopoeia (USP43), European Pharmacopoeia (EP10) for water for injection.

PRINCIPLE 工作原理

合格的原料水由多级泵增压后进入管道冷凝器2、利用废热给原料水升温。 然后进入预热器2、预热器1、热交换后进入蒸发器经料水分配器喷射在加 热管内壁,使料水在管壁成膜状流动,被工业蒸汽加热汽化,气化后产生 的夹带水滴的二次蒸汽,从蒸发室下端进入汽水分离装置,经三级分离后 成为超纯的纯蒸汽。

The qualified raw water is pressurized by the multi-stage pump and then enters the pipeline condenser 2, uses waste heat to heat the raw water, and then enters the preheater 2 and the preheater 1. After heat exchange, it enters the evaporator and is sprayed into the heating tube by the material water distributor. Make material water to flow in a film status on the tube wall, which will be heated

and vaporized by industrial steam. The secondary steam with water droplets generated after gasification enters the steam-water separation device from the lower end of the evaporation chamber, and becomes ultra-pure steam after three-stage separation.

FEATURE 产品特点

- 1、结构形式:蒸发器、预热器和冷凝器均为双管板设计,采用内管板胀接外焊接工艺,避免交叉污染。
- 2、分离装置: 具有降膜蒸发、重力分离及螺旋绕流三级分离。
- 3、材料材质:与原料水、纯蒸汽、纯蒸汽冷凝水接触的部分全部采用SS316L。
- 4、保温隔热:蒸发器、预热器均采用硅酸铝针刺毯,具有延伸性好,质量轻,隔热性极佳,有较强的稳定性。
- 5、表面处理: 内外表面电化学抛光, 有效保证不锈钢表面的光洁度。

- 6、节能降耗:蒸发器和分离器形成一个庞大的连通器,热量得到充分利用。整台设备可以在很短时间内从待机状态达到最大生产能力。 利用液位控制原料水得到充分利用,做到充分的节能降耗。预热器2利用工业蒸汽凝结水来预热,起到节约能源的作用。
- 7、管路尽可能采用不锈钢管直接拉伸弯管,避免焊接。管路与配件焊件,尽可能使用氩气保护自动焊接(单面焊双面成型工艺), 保证焊接质量,焊后电化学抛光。
- 8、提供内窥镜检查照片、焊点图、压力测试及酸洗钝化报告及系统设计文件等验证资料。
- 9、控制系统采用HMI+PLC全自动控制,操作界面简便。可提供各种通讯模式。控制系统权限级数:至少可设置三级权限。
- 10、在线监控电导率、温度和流量等参数。记录仪即可选择无纸记录仪也可选择有纸记录仪,对关键参数进行记录和打印。
- 11、控制系统可选配电子签名、电子记录,使系统控制具有审计追踪功能,并满足GAMP 5要求及符合21 CFR PART 11要求。
- 1. Structure: external preheater, condenser and first effect evaporator are designed with double tubesheets, and the inner tubesheet expansion welding process is adopted to avoid cross conta mination.
- 2. Separation device: with falling film evaporation, gravity separation and spiral flow three-stage separation.
- 3. Material: SS316L is used for all parts in contact with raw water, water for injection and secondary pure steam.
- 4. Heat preservation and heat insulation: evaporator, preheater and condenser are all made of aluminosilicate needle felt, with good extensibility, light weight, excellent heat insulation and strong stability.
- 5. Surface treatment: internal and external surface electrochemical polishing, effectively ensure the surface finish of stainless steel.
- 6. Energy saving and consumption reduction; due to the secondary steam being used step by step in each efficiency, the multi effect distilled water machine has a high utilization rate of industrial steam and has obvious energy saving effect. With the increase of evaporator efficiency, the energy-saving effect is more obvious. At the same time, the amount of cooling water also decreased with the increase of efficiency. The five effect distilled water machine produced by our company uses a small amount of cooling water, and the six effect distilled water machine does not need cooling water.
- 7. Stainless steel pipe shall be used as far as possible to directly stretch the elbow to avoid welding. As far as possible automatic welding with argon protection shall be used for pipeline and fittings weldments(single sidewelding and double side forming process) to ensure the welding quality and electrochemical
- 8. Provide endoscopy photos, solder joint diagram, pressure test and pickling passivation report, system design documents and other verification data.
- 9. The control system adopts HMI + PLC automatic control, and the operation interface is simple. Various communication modes can be provided. Control system authority level: at least three levels of authority can be set.
- 10. Online monitoring of conductivity, temperature and flow parameters. The recorder can select paperless recorder or paper recorder to record and print the key parameters.
- 11. The control system can be equipped with electronic signature and electronic record, so that the system control has udit trail function, and meets the requirements of gamp 5 and 21 CFR Part 11.

PARAMETER 参数表

工作压力0.3MPa的情况下 industrial steam pressure 0.3MPa

	产量 Capacity (L/h)	工业蒸汽耗量 Industrial steam consumption (L/h)	原料水耗量 Feed water consumption (L/h)	外形尺寸 Dimensions (mm)
CZQ100	≥100	110	110	1200×800×2900
CZQ200	≥200	220	220	1400×1000×3350
CZQ300	≥300	330	330	1550×1100×3650
CZQ400	≥400	440	440	1500×1100×4100
CZQ500	≥500	550	550	1900×1310×3800
CZQ750	≥750	825	825	1900×1310×4100
CZQ1000	≥1000	1100	1100	2000×1360×4500
CZQ1500	≥1500	1650	1650	2400×1500×4800
CZQ2000	≥2000	2200	2200	2400×1500×5100



DISTRIBUTION SYSTEM / PIPELINE

分配系统/输送管道



根据客户现场实际需要及消毒要求方式进行设计,以GMP、ISPE工程 指南和FDA的规范为设计理念,合理利用空间,使用操作方便,选择 优质的洁净管件, 做到设计、安装无死角、无污染, 回流控制合理、 完全满足用户的要求及验证的要求。

Design according to the actual needs of the customer's site and the disinfection requirements, with GMP, ISPE engineering guidelines and FDA specifications as the design concept, rational use of space, convenient use and operation, and selection of high-quality clean pipe fittings. So that the design and installation are free of dead ends and no contamination. The reflux control is reasonable and fully meets the user's requirements and verification requirements.

FEATURE 产品特点

- 1、安装紧凑、布局美观、合理利用空间
- 2、流程优化、方便操作
- 3、零死角设计
- 4、全自动焊接
- 5、内窥镜检查
- 6、压力测试、酸洗钝化处理

- 1. Compact installation, beautiful layout, reasonable use of space
- 2. Process optimization and convenient operation
- 3. Zero dead angle design
- 4. Fully automatic welding
- 5. Endoscopy detection.
- 6. Pressure test, pickling passivation treatment

AND PLATE HEAT EXCHANGER



精鹰流体工程与多家知名品牌换热器生产商合作, 在了解换热器的技术性能和工作参数后,进行安装工艺的优化设计。

列管式换热器

- 1、换热器分为单管板和双管板,列管式能承受高温和高压
- 2、选用316L优质无缝钢管做换热管, 延长使用寿命
- 3、O型密封圈设计,符合FDA、USP class VI 要求
- 4、换热器无死角、无污染、易于清洗
- 5、杜绝微生物的滋生,更好的满足验证要求

板式换热器

- 1、板式蒸发器/换热器主要应用于化工、制药、啤酒、饮料和乳制品等行业
- 2、具有无菌/食品级接口,符合GMP要求
- 3、换热效率优于管壳式换热器,安装紧凑、占地小,且扩容、维护方便
- 4、材质可选SUS304、SUS316L、Ti等,满足不同的工况



WEMAC Fluid Engineering cooperates with many well-known brand heat exchanger manufacturers to optimize the design of the installation process after understanding the technical performance and working parameters of the heat exchanger.

Tube sheet heat exchanger

- 1. The heat exchanger has single tube plate and double tube plate, and the tube plate type can withstand high temperature and high pressure.
- 2. Adopt SS316L high-quality seamless steel pipe as heat exchange tube to prolong the service life.
- 3. O-shaped sealing ring design meets FDA, USP class VI requirements
- 4. The heat exchanger has no dead ends, no contamination, and easy for
- 5. Prevent the breeding of microorganisms and better meet the verification requirements

Plate type heat exchanger

- 1. Plate evaporators/heat exchangers are mainly used in the chemical, pharmaceutical, beer, beverage and dairy industries.
- 2. It has a aseptic/food grade interface and meets GMP requirements
- 3. Heat exchange efficiency is better than shell-and-tube heat exchangers. compact installation, small occupation, and convenient expansion and
- 4. The material can adopt SUS304, SUS316L, Ti, etc. to meet different working conditions.

PARAMETER 技术参数

型号 Model	单板面积 Single plate area	板片材质 Material of plate	垫片材质 Material of gasket	最大粘度 Max Viscosity	蒸发能力 Ability of evaporation
VAP100	0.25m²	SUS304.SUS3 16L,Ti	NBR.EPDM机械固定	3000cP	0.05-0.5t/h
VAP200	0.55m²	SUS304.SUS316L,Ti	NBR.EPDM机械固定	3000cP	0.1-2t/h
VAP300	0.85m²	SUS304.5/S316L	NBR.EPDM校粘	3000cP	0.5-5t







LIQUID PREPARATION SYSTEM

配料系统



山东精鹰为无菌制剂、单抗、生物疫苗、血液制品等行业提供针剂制水系统 及配料系统的设计、制造、安装和验证支持。



WEMAC provides customers with design, manufacturing, installation and verification support of injection water system and liquid preparation system in sterile preparations, monoclonal antibodies, biological vaccines, blood products and other industries.

根据客户现场实际需要及消毒要求方式进行设计,以GMP、ISPE工程 指南和FDA的规范为设计理念,合理利用空间,使用操作方便,选择 优质的洁净管件,做到设计、安装无死角、无污染,回流控制合理、 完全满足用户的要求及验证的要求。

Design according to the actual needs of the customer's site and the disinfection requirements, with GMP, ISPE engineering guidelines and FDA specifications as the design concept, rational use of space, convenient use and operation, and selection of high-quality clean pipe fittings. So that the design and installation are free of dead ends and no contamination. The reflux control is reasonable and fully meets the user's requirements and verification requirements.

CIP SYSTEM

清洗系统



FEATURE 产品特点

- 1、适用于大、中、小型各类设备清洗。
- 2、结构紧凑,占地面积小,安装、维护方便。
- 3、洗涤剂可循环使用,利用率高。
- 4、易损失少,使用寿命长。
- 5、能方便、有效地对储罐及管道等生产设备进行就地清洗,其整个 清洗过程均在密封的生产设备,储罐容器和管道中运行,从而大 大减少了二次污染机会。
- 6、清洗工作可实现程序化和自动化。
- 7、体外循环系统,可有效减少能耗。
- 8、有单罐、双罐及多罐供用户选择。

- 1. Suitable for cleaning of large, medium and small equipments.
- $2. \ Compact \ structure, \ small \ floor \ space, \ convenient \ in stall ation \ and \ maintenance.$
- 3. Detergent can be recycle used with high utilization rate.
- 4. Less wearing parts, with long service life.
- 5. Can easily and effectively in-place clean the storage tanks, pipelines and other production equipments. The entire cleaning process runs in sealed production equipment, storage vessels and pipelines, thereby greatly reducing the chance of secondary contamination.
- 6. The cleaning work can be programmed and automated.
- 7. External circulation system can effectively reduce energy consumption.
- 8. There are single tank, double tank and multiple tanks for users to choose.







CONCENTRATED PREPARATION TANK AND DILUTE PREPARATION TANK

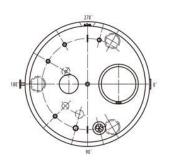
浓配罐/稀配罐

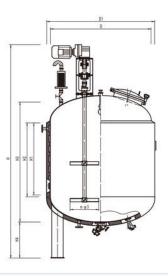


FEATURE 产品特点

- 1、罐体均采用立式双层结构;
- 具有加热和保温功能: 夹层内缠绕螺旋带通蒸汽加热或通冷 水冷却, 保温材料采用玻璃纤维针刺毡;
- 3、凡与流体接触的零部件均采用316L材质,其余采用304材质;
- 4、配有温度传感器、卫生级液位传感器、清洗器和空气呼吸器;
- 5、电机减速机可选用德国等著名品牌,亦可加变频调速器实现 无级调速;
- 6、搅拌轴的密封采用卫生级机械密封;
- 7、接口采用ISO2037快装卡盘式;
- 8、可按客户要求单独设计、加工。

- 1. The tank cylinder adopts a vertical double-layer structure .
- which has heating and heat preservation functions: the interlayer spiral belt is heated by steam or cooled by cold water, and the heat preservation material is made of glass fiber needled felt.
- All parts in contact with fluid are made of SS316L, and the rest parts are made of Ss304.
- 4. Equipped with temperature sensor, sanitary level sensor, spray ball and vent filter;
- The motor reducer can be adopted with Germany brand, and can also with a frequency converter to achieve stepless speed regulation.
- 6. The seal of the mixing shaft adopts sanitary mechanical seal.
- 7. The interface adopts ISO2037 quick-fit type.
- 8. It can be individually designed and processed according to customer requirements.





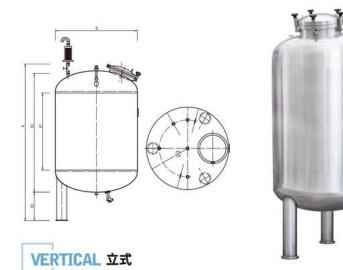
PARAMETER 技术参数

코号	规格 (L)		9:	号尺寸 (mm) Refere	nce Size(n	nm)		V-	114
Model	Specification -ion	D	D1	п-ф3	н	ні	H2	нз	Н4	功率(kw Power
PG100	100	600	700	ф200	1898	380	300	665	442	0.37
PG200	200	800	900	ф250	1939	350	374	710	445	0.37
PG300	300	800	900	ф250	2039	450	474	812	445	0.55
PG500	500	900	1000	ф300	2270	640	664	1038	445	0.55
PG600	600	900	1000	ф300	2419	830	853	1228	404	0.55
PG800	800	1000	1100	ф350	2659	890	913	1326	403	0.75
PG1000	1000	1100	1200	ф350	2710	900	920	1316	403	0.75
PG1500	1500	1300	1400	ф400	2848	960	984	1514	403	0.75
PG2000	2000	1400	1500	2-ф400	3027	1100	1120	1692	403	1.5
PG2500	2500	1500	1600	2-ф450	3169	1200	1220	1832	404	1.5
PG3000	3000	1600	1700	2-ф500	3308	1300	1325	1970	404	1.5
Pg4000	4000	1900	2000	2-ф500	3273	1150	1174	1936	404	1.5
Pg5000	5000	1900	2000	2-ф600	3623	1500	1524	2286	404	2.2
PG6000	6000	2100	2200	2-ф600	3657	1430	1456	2324	405	2.2
PG8000	8000	2300	2400	2-ф700	3808	1500	1527	2472	406	3
PG10000	10000	2500	2600	2-φ750	4085	1700	1716	2748	406	3



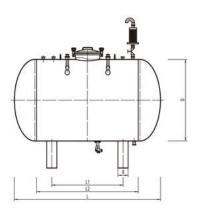
SINGLE LAYER LIQUID STORAGE TANK

316L/304单层储液罐



型号	规格 (L)	规格(L) 参考尺寸(mm)Reference Size(mm)								
Model	Specification -ion	D	D1	н	н	H2	нз	Н4		
CHL300	300	800	900	1484	460	461	820	400		
CHL500	500	900	1000	1587	530	530	928	400		
CHL1000	1000	1100	1200	1878	750	750	1356	400		
CHL2000	2000	1300	1400	2463	1220	1220	1926	400		
CHL3000	3000	1600	1700	2395	1220	1100	2070	400		
CHL4000	4000	1800	1900	2557	1220	1220	2220	400		
CHL5000	5000	1900	2000	2637	1220	1220	2220	400		
CHL6000	6000	2000	2100	2806	1380	1380	2206	400		
CHL8000	8000	2200	2300	3226	1500	1500	2680	400		
CHL10000	10000	2400	2500	3450	1580	1780	2780	400		





HORIZONTAL 卧式

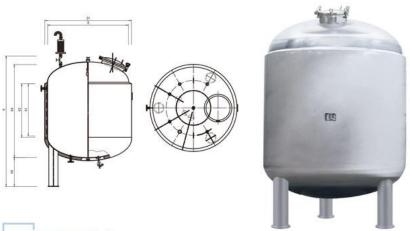
型号	規格 (L)	参考尺寸 (mm) Reference Size(mm)							
Model	Specification -ion	D	L	L1	L2	В			
CD1000	1000	1000	1606	730	1050	150			
CD2000	2000	1200	2156	1050	1500	150			
CD3000	3000	1300	2656	1300	1950	150			
CD4000	4000	1500	2708	1300	1900	200			
CD5000	5000	1600	2908	1400	2050	200			
CD6000	6000	1700	3108	1450	2200	200			
CD8000	8000	1900	3358	1650	2350	250			
CD10000	10000	1900	4058	2050	3000	250			
CD15000	15000	2100	4912	2500	3800	300			
CD20000	20000	2300	5472	2800	4200	300			

配有卫生级液位传感器、清洗器和空气呼吸器; 316L或304材质,内表面镜面抛光Ra0.4,外表面亚光处理; 接口采用ISO2037标准快装卡盘式; 可按客户要求单独设计、加工。 Equipped with sanitary level sensor, spray ball and vent filter; \$\$3161, or \$\$304 material, internal surface mirror polishing Ra 0.4. External surface Matt treatment; The interface adopts ISO2037 standard quick-fit type; It can be designed and processed separately according to customers' requirements.



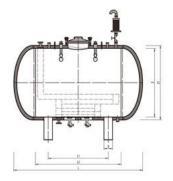
SS316L JACKET AND INSULATION INJECTION WATER STORAGE TANK

316L保温加热注射用水储罐



VERTICAL 立式

호용	规格 (L)		参考尺寸 (mm) Reference Size(mm)								
Model	Specification -ion	D	D1	н	н	H2	нз	Н4			
CHL300	300	800	900	1484	460	461	820	400			
CHL500	500	900	1000	1587	530	530	928	400			
CHL1000	1000	1100	1200	1878	750	750	1356	400			
CHL2000	2000	1300	1400	2463	1220	1220	1926	400			
CHL3000	3000	1600	1700	2395	1220	1100	2070	400			
CHL4000	4000	1800	1900	2557	1220	1220	2220	400			
CHL5000	5000	1900	2000	2637	1220	1220	2220	400			
CHL6000	6000	2000	2100	2806	1380	1380	2206	400			
CHL8000	8000	2200	2300	3226	1500	1500	2680	400			
CHL10000	10000	2400	2500	3450	1580	1780	2780	400			





HORIZONTAL 卧式

型号	规格 (L)	参考尺寸 (mm) Reference Size(mm)							
Model	Specification -ion	D	L	L1	L2	В			
CHW1000	1000	1000	1696	730	1050	150			
CHW2000	2000	1200	2267	1050	1500	150			
CHW3000	3000	1300	2746	1300	1950	150			
CHW4000	4000	1500	2796	1300	1900	200			
CHW5000	5000	1600	3002	1400	2050	200			
CHW6000	6000	1700	3202	1450	2200	200			
CHW8000	8000	1900	3444	1650	2350	250			
CHW10000	10000	1900	4144	2050	3000	250			
CHW15000	15000	2100	4910	2500	3800	300			
CHW20000	20000	2300	5492	2800	4200	300			

具有加热和保温功能。夹层内缝绕螺旋带通蒸汽加热或通冷水冷却,保温材料采用玻璃纤维针刺毡。配有温度传感器,卫生级液位传感器、清洗器和空气呼吸器;内胆为316L或304材质,内表面镜面抛光RaO.4,外表面亚光处理;可按客户要求单独设计、加工。

With heating and heat preservation functions. The spiral belt wound in the interlayer is heated by steam or cooled by cold water. And the insulation material is made of glass fiber needled felt. Equipped with temperature sensor, sanitary level sensor, spray ball and vent filter;

the internal tank is made of SS316L or SS304, the internal surface is mirror polished Ra0.4, and the external surface is matted; it can be individually designed and processed according to customer requirements.





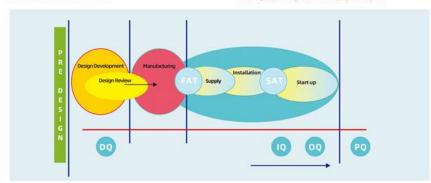
GMP VERIFICATION SERVICE

GMP验证服务

项目管理 Project Management

山东精鹰作为制药用水系统的专业供应商,遵循GMP要求,项目 按照以下步骤贯穿整个项目生命周期.

WEMAC as a professional supplier of pharmaceutical pure water system, strictly follow the requirement of GMP. The project in accordance with the following steps throughout the whole project life cycle.



报价前与客户讨论风险管理,并可协助客户制作符合新版GMP的URS; 接到订单后针对项目制定OPP和项目时间表,召开启动会议; 设计后提供设计文件进行设计确认,把可能发现的关键不一致问题解 决在萌芽阶段;制造阶段严格按内部质量管理体系做好各项检测工作, 并保存好记录和报告;

Discuss risk management with customers before quotation, and can assist customers in making URS in compliance with the new version of GMP; After receiving the order, formulate QPP and project timetable for the project, and hold a kick-off meeting;

Provide design documents for design confirmation after design, and solve the key inconsistencies that may be found in the embryonic stage; in the manufacturing stage, perform various inspections in strict accordance with the internal quality management system, and keep records and reports;

焊接

严格执行焊接工艺 优秀焊工持证上岗

焊口100%外观检查

焊缝20%X射线检查

全程内窥镜跟踪检查

焊接记录同步于焊接过程

焊口和焊点图——对应

验证资料

根据客户URS, 在工程项目设计、加工、焊接、安装、测试 的同时, 形成本工程所需的资料文件, 最终提交一套符合

GMP验证需要的系列文件

项目质量计划 (QPP)

工艺管道部件的材质证明单

仪表出厂校验报告 焊接记录报告

现场安装测试方案及报告

可提供DQ/IQ/OQ方案

相关文件

功能说明

详细设计说明

接触产品的部件材质证明

仪表出厂校验报告

焊接记录

内窥镜检查记录

光洁度检查记录

各种相关SOP

DQ/IQ/OQ方案

Welding

Strictly implement the welding process

Excellent welders work with certificates

100% appearance inspection of welded joint

20% X-ray inspection of weld

Endoscope follow-up inspection

Welding records are synchronized with the welding process

Welding joint and welding point diagram-corresponding

Verification Documenta

According to customer URS, in engineering project design, processing, welding, installation and testing. At the same time, form the required data documents for this project, and finally submit a set of series of documents required for GMP verification

Project Quality Plan (QPP)

Material certificate of process piping components

Instrument factory calibration report

Welding record report

Site installation test plan and report

DQ / IQ / OQ solutions available

Related documents

Function Description

Detailed design description

Proof of the material of the parts in contact with the product

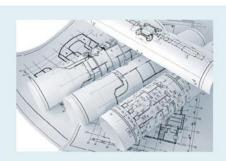
Instrument factory calibration report

Welding record

Endoscopy records

Finish inspection record Various related SOPs

DQ/IQ/OQ scheme











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