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楚天华通
TRUKING WATERTOWN

楚天华通医药设备有限公司

TRUKING WATERTOWN PHARMACEUTICAL EQUIPMENT CO.,LTD.

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Thermal Inactivation

热力废液灭活系统

楚天华通医药设备有限公司

TRUKING WATERTOWN PHARMACEUTICAL EQUIPMENT CO.,LTD.

让世界制药工业插上智慧的翅膀

Equip global pharmaceutical manufacturing industry with intelligent wings.

TRUKING

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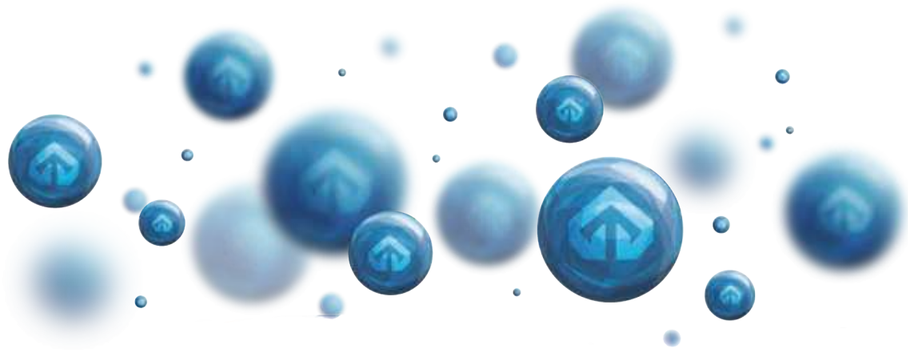


楚天华通医药设备有限公司系楚天科技股份有限公司全资子公司，始建于1993年，是目前亚洲领军制药用水系统（制备、储存和分配）、配液系统、不锈钢压力容器、污水处理、蒸发浓缩结晶、换热器研发制造基地，装备及制造工艺处于行业优级水平，员工总数1300余人，资产总额20亿元，服务于全球1000余家制药企业。

公司位于长春九台经济开发区，是中国制药装备行业协会理事单位，中国医药设备工程协会、中国膜工业协会会员单位，获评定为国家级高新技术企业、吉林省专精特新企业、吉林省级企业技术中心，获得省级创新型科技企业、长春市百强民营企业、长春市科技型小巨人企业等荣誉。公司拥有中国特种设备压力容器D级（10MPa以下的一类、二类、三类压力容器）设计与制造资质、压力管道（GC2）安装许可证、建筑机电安装工程专业承包贰级资质、环保工程专业承包贰级、环境工程设计专项（水污染防治工程）乙级、美国ASME（U）钢印设计与制造资质、欧盟CE（PED、MD）认证资质。截至2023年4月，公司共提出中国专利申请320项，有效专利180项，另提出1件PCT国际专利申请。产品已出口美国、意大利、比利时、希腊、土耳其、俄罗斯、韩国、泰国、越南、印尼、印度、埃及、沙特、摩洛哥、秘鲁等30多个国家和地区，国际市场占有率正逐年快速提升。

公司拥有经验丰富的研发技术团队,覆盖工程设计、项目管理、测试调试、验证与咨询服务，联合楚天科技、德国ROMACO集团、四川省医药设计院共同承接制药企业EPCM总包服务，为制药企业提供工程工艺优化、产品的全生命周期管理与服务。

2021年公司确认新建楚天华通医药装备智能制造产业园项目，位于长春市九台经济技术开发区中古医药产业园。项目新购地36.1117万平方米，计划在5年内分三期完成项目整体建设任务，项目建成后，将崛起楚天华通研发中心大楼、智能车间、员工公寓以及商务接待中心等现代化智能配套公用工程。一期工程建筑面积6万平米，预计2023年7月投产。作为楚天华通年产5000台套医药装备的智能制造基地，楚天华通医药装备智能制造产业园项目完成后将大幅提升企业产能，将进一步推动企业战略目标的实现。

公司坚持“做受尊敬的人、造受尊敬的产品、办受尊敬的企业”的核心价值观，秉承“要么唯一，要么第一”的理念，弘扬“因为执着，所以卓越”的精神，将楚天华通打造成全球制药用水系统领军企业之一。

Truking Watertown Pharmaceutical Equipment Co., LTD., a wholly-owned subsidiary of Truking Technology Limited, was founded in 1993. It is the leading R&D and manufacturing base of pharmaceutical water system (preparation, storage and distribution), liquid preparation system, stainless steel pressure vessel, sewage treatment, evaporation, crystallization and heat exchanger in Asia. With more than 1300 employees and 2 billion yuan of assets, the company serves more than 1000 pharmaceutical enterprises around the world.

Truking Watertown is located in Jiutai Economic Development Zone, Changchun. It is a member of China Pharmaceutical Equipment Industry Association, China Pharmaceutical Equipment Engineering Association and China Membrane Industry Association. It has been rated as a national high-tech enterprise, Provincial Specialized and Sophisticated Enterprise, Provincial Enterprise Technology Center. It has been honored as provincial innovative technology Enterprise, Changchun Top 100 Private Enterprise, and Changchun Small Giant Technology Enterprise. Truking Watertown has Chinese special equipment Class D (Class I, Class II and Class III below 10MPa) pressure vessel design and manufacturing license, Pressure pipeline (GC2) installation license, construction mechanical and electrical installation engineering contracting Class II, environmental engineering contracting Class II, environmental engineering design special (water pollution control engineering) Class B, ASME(U) steel seal design and design manufacturing qualification, EU CE(PED, MD) certification qualification. Truking Watertown has applied for 320 patents, 180 patents of which have been authorized until April 2023, and one PCT international patent application. Products have been exported to the United States, Italy, Belgium, Greece, Turkey, Russia, South Korea, Thailand, Vietnam, Indonesia, India, Egypt, Saudi Arabia, Morocco, Peru and other 30 countries and regions, the international market share is rapidly increasing year by year.

Truking Watertown has an experienced R&D technical team, covering engineering design, project management, testing and commissioning, validation and consulting services. Together with Truking Technology, Germany ROMACO Group and Sichuan Pharmaceutical Design Institute, the company jointly undertakes EPCM general contract services for pharmaceutical enterprises, providing engineering process optimization and product lifecycle management and services for pharmaceutical enterprises.

In 2021, Truking Watertown pharmaceutical equipment Intelligent Manufacturing Industrial Park project started, located in Jiutai Economic and Technological Development Zone of Changchun Medicine Industrial Park. The new plant occupies 361,117 square meters. It is planned to complete the overall construction in three phases within 5 years. After the completion of the construction, Truking Watertown R&D Center building, intelligent workshop, employee apartment and business reception center and other modern intelligent supporting utilities will be used. The first phase of the project covers a construction area of 60,000 square meters and is expected to be put into operation in July 2023. As base of Truking Watertown with an annual output of 5,000 sets, pharmaceutical equipment intelligent manufacturing Industrial Park will greatly improve the enterprise's production capacity after the completion of the project, which will further promote the realization of the strategic objectives of the enterprise.

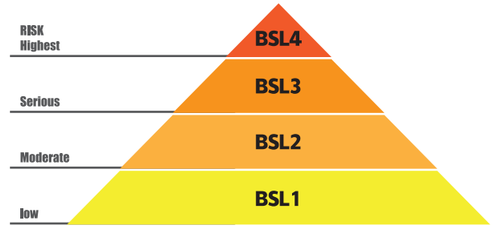
We insist on the core value of being respected person, making respected product and running respected enterprise and adhere to the philosophy to be the unique or to be the first and promote the spirit of Because of persistence, we are superexcellent to make Truking Watertown be one of the leading pharmaceutical water system enterprises all over the world.

生物安全等级 / Biosafety Level

楚天华通致力于制药企业提供合规、高效、可靠的生物废液灭活解决方案，可满足包括实验室、小试中试、大生产在内的多种生产模式需要。为制药行业生产过程中的废液合规排放提供可靠支持，推动制药行业向绿色循环能源经济模式健康发展。

TRUKING WATERTOWN is committed to providing compliant, efficient and reliable biological waste liquid inactivation solutions for pharmaceutical companies, which can meet the requirements of various production modes including laboratory, small-scale, pilot- scale, and large-scale production. Provide reliable support for the compliant discharge of waste liquid in the production process of the pharmaceutical industry, and promote the healthy development of the pharmaceutical industry to a green circular energy economic model.

生物废液灭活系统等级依据生物安全等级划分，生物安全等级是针对生物危害的不同程度而确定的，其中包括对实验人员、实验室，乃至环境保护的要求，通常按生物危害等级将微生物和生物医学实验室的安全相应划分为4级，分别为：BSL-1、BSL-2、BSL-3、BSL-4。



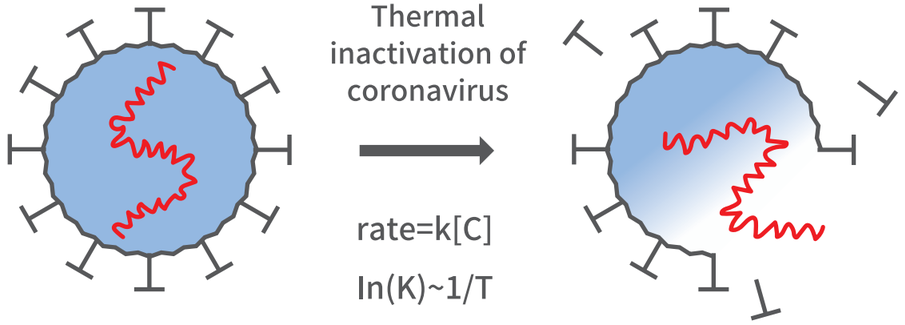
The level of biological waste liquid inactivation system is divided according to the level of biosafety. Biosafety level is determined according to different degrees of biohazard, including requirements for laboratory personnel, laboratory and even environmental protection. Generally, the safety of microbial and biomedical laboratory is divided into 4 levels according to biohazard level, namely: BSL-1, BSL-2, BSL-3, BSL-4.

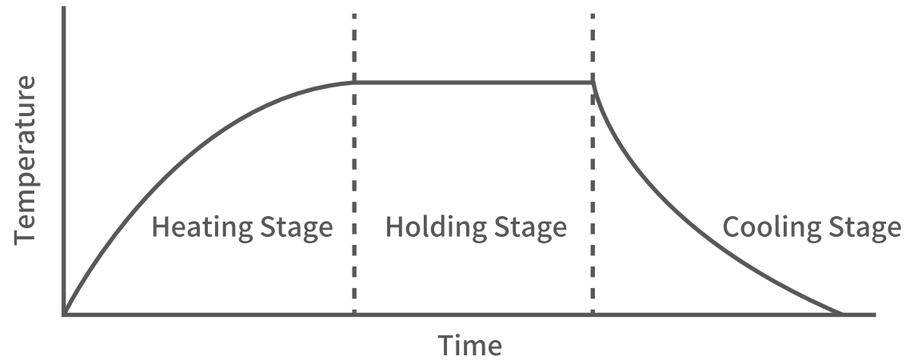
生物安全等级 Biological safety level	生物危害程度 Degree of biological hazard	举例 Example
BSL-1	**低个体危害，低群体危害 / Low individual harm, low group harm** 对人体、动植物或环境危害较低、不具有对健康成人、动植物致病的致病因子。 Low harm to human body, animals and plants or environment, no pathogenic factors for healthy adults, animals and plants.	**大肠杆菌的非致病性菌株** Non-pathogenic strains of E. coli
BSL-2	**中等个体危害，有限群体危害 / Moderate individual harm, limited group harm** 对人体、动植物或环境具有中等危害或具有潜在危险的致病因子、对健康成人、动植和环境不会造成严重危害。具有有效的预防和防止措施。 Disease-causing agents that are moderately harmful or potentially dangerous to human body, animals and plants or the environment, and do not cause serious harm to healthy adults, animals and the environment. With effective prevention and prevention measures.	**金黄色葡萄球菌** Staphylococcus aureus
BSL-3	**高个体危害，低群体危害 / High individual hazard, low group hazard** 对人体、动植物具有高度危害性，通过直接接触或气溶胶使人传染上严重的甚至致命疾病，或对动植物和环境具有高度危害的致病因子，通常有预防和治疗措施。 It is highly harmful to human body, animals and plants, and can infect people with serious or even fatal diseases through direct contact or aerosol, or pathogenic factors that are highly harmful to animals and plants and the environment. Prevention and treatment measures are usually available.	**结核分枝杆菌** Mycobacterium tuberculosis
BSL-4	**高个体危害，高群体危害 / High individual hazard, high group hazard** 对人体、动植物或环境具有高度危害性，通过气溶胶途径传播或者传播途径不明，或未知的、高度危险的致病因子，没有预防和防治措施。 It is highly hazardous to the human body, animals and plants or the environment. It is transmitted by aerosol route or unknown route of transmission, or unknown and highly dangerous pathogenic factors, and there is no prevention and control measures.	**埃博拉病毒 马尔堡病毒** Ebola, Marburg

热力灭活原理 / Thermal Inactivation Principle

细菌蛋白质、核酸等化学结构是由氢键连接的，而氢键是较弱的化学键，当处于高温环境时，氢键遭到破坏，蛋白质、核酸、酶等结构也随之被破坏，蛋白质变性或凝固、酶失去活性，使细菌及病毒失去其生物学活性，导致死亡。

Chemical structures such as bacterial proteins and nucleic acids are connected by hydrogen bonds, and hydrogen bonds are weaker chemical bonds. When in a high temperature environment, the hydrogen bonds are destroyed, and the structures of proteins, nucleic acids, enzymes, etc. are also destroyed. Protein denaturation or coagulation, enzyme inactivation, so that bacteria and viruses lose their biological activity, resulting in death.





热力灭活参数 / Thermal Inactivation Parameter

对于生物灭活工艺，其核心参数为温度和时间，设备工艺设计通常以F0数值计算依据。

F0值为一定灭菌温度（T）下，Z为10°C时所产生的灭菌效果与121°C，Z值为10°C所产生的灭菌效果相同时所相当的时间（min）。也就是说，不管温度如何变化，t分钟内的灭菌效果相当于在121°C下灭菌F0分钟的效果。

For biological inactivation process, its core parameters are temperature and time, and the equipment process design is usually based on F0 numerical calculation.

F0 value is the time (min) during which the sterilization effect at a certain sterilization temperature (T) and Z at 10°C are the same as the sterilization effect at 121°C and Z at 10°C. That is, regardless of temperature changes, the effect of sterilization in t minutes is equivalent to the effect of sterilization in F0 minutes at 121 ° c.

$$F_0 = \Delta t \sum 10^{\frac{T-121}{z}}$$

物理F0值数学表达式：F0=Δt Σ10 T-121/Z

生物F0值数学表达式：

F0=D121°C×（lgN0-lgNt）为灭菌后预计达到的微生物残存数，即染菌度概率。

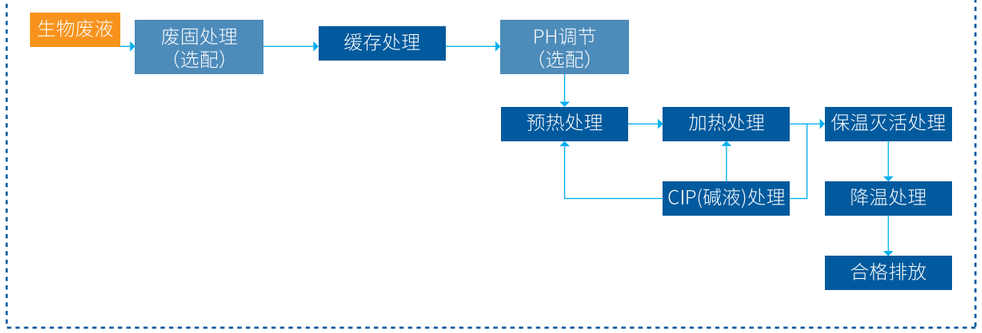
处理温度 Temperature	处理时间 Processing time	F0
121.1°C	30min	30
125°C	12min	30
130°C	4min	30
135°C	1.5min	30
140°C	24s	30
150°C	2.4s	30

灭菌温度与持续时间参数组合
Sterilization temperature and duration parameter combination

热力灭活工艺 / Thermal Inactivation Process

一、TC热力连续式灭活工艺

1、工艺流程 / Process



运行流程：生物废液经由废固处理单元（选配）进入缓存单元，通过泵输送至换热单元及加热单元内加热至灭菌温度，加热的废液进入循环保温单元内在规定温度下保持设定时间后达到灭菌效果，循环降温后排放，系统内废液持续排放，无滞留状态。

Running processes: biological waste liquid through a solid waste treatment unit (optional) enter the buffer unit, through the pump to heat units and heating units heated to the sterilization temperature, the heating liquid into the circulation heat preservation unit internal rules set temperature keeping time after sterilization effect, circulation cooling after discharge, waste liquid in the system continuous discharge, without stop.

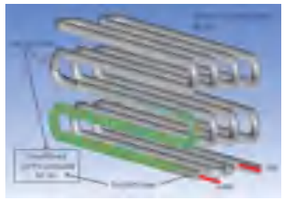
2、工艺特点 / Process characteristics

- **节能降耗：**系统灭活后排放热量系统内回收预热使用，能源利用效率高。
- **加热均匀：**废液持续流动加热，加热均匀，不存在加热温度梯度问题。
- **设备体积：**不间断处理废水, 不会囤积废水，无需较大缓冲罐。
- **应变能力：**可以精确的调节温度而不用更换设备, 适合试验参数变化。
- **自动清洁：**系统配置CIP单元，可定期进行自动除垢。
- **灵活灭菌：**整体灭活与分区灭活可选。关键元件可单独进行灭菌操作。
- **过程参数：**配置无纸记录仪，可对设置的灭菌温度即灭菌时间进行记录及验证操作。
- **冗余设计：**关键部件均采用冗余设计，单泵故障可隔离灭菌，灭菌后拆卸维修。
- **结构设计：**设备模块化设计，整体框架式撬装结构，底部设置整体接水盘，收集设备运行意外泄露的废液以及维护时的排放废水再处理。

- Energy saving and consumption reduction: after the system is inactivated, the heat emitted is recovered and preheated in the system for use, resulting in high energy use efficiency.
- Uniform heating: waste liquid is heated by continuous flow, heating is uniform, there is no heating temperature gradient problem.
- Device volume: Continuously processes wastewater without storing it, eliminating the need for a large buffer tank.
- Strain capacity: can precisely adjust the temperature without changing equipment, suitable for test parameters change.
- Automatic cleaning: The system is equipped with a CIP unit that automatically descales at regular intervals.
- Flexible sterilization: block inactivation and partition inactivation are optional. Key components can be sterilized separately.
- Process parameters: equipped with a paperless recorder, you can record and verify the sterilization temperature (sterilization time) set.
- Redundant design: key components are redundant design, single pump failure can be isolated and sterilized, disassembly and maintenance after sterilization.
- Structure design: modular equipment design, the overall frame type skid-mounted structure, the bottom set overall water tray, collect accidental leakage of waste liquid equipment operation and maintenance of waste water for retreatment.

3、部件单元 / Component unit

·保温灭活单元 / Thermal insulation inactivation unit



设计要点 Key points of Design：

保持时间需大于等于F0值对应温度下的处理时间。

例如：处理温度选取135℃，F0值30，对应处理时间为90s，故保温灭活单元需要维持废液流动时间≥90s。

The holding time must be greater than or equal to the processing time at the temperature corresponding to the F0 value.

For example, the treatment temperature is set to 135℃, the F0 value is 30, and the corresponding treatment time is 90s. Therefore, the heat preservation and inactivation unit needs to maintain the flow time of waste liquid ≥90s.

结构特点 Structural features：

三维弯管，减少管道焊点，降低泄露风险，提高管道一致性。

硬壳保温结构，坚固耐用。

端头活结，便于后期维护。

模块化设计，便于后期处理能力及参数扩展。

Three-dimensional pipe bending, reduce solder joints, reduce leakage risk, improve pipeline consistency.
Hard shell insulation structure, strong and durable.
Unfixed connection end, easy to maintain.
Modular design, easy to post processing and parameter expansion.

·换热单元 / Heat exchange unit

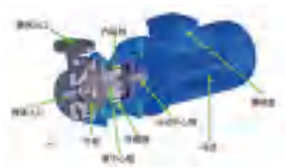
单通道设计，降低结垢风险。同时整体可拆卸，可清洗。

两种流体介质同心螺旋流动，冷热流体完全逆流换热，热媒由中心孔进入由内向外流出，冷流体由边缘切向流进入，换热效率高。

Single channel design reduces scaling risk. At the same time the whole removable, can be cleaned.

The two fluid media flow concentrically in spiral, the hot and cold fluid completely countercurrent heat transfer, the hot medium enters from the center hole by inward outflow, the cold fluid enters from the edge tangential flow, high heat transfer efficiency.

·磁力泵 / Magnetic pump



泵传动采用磁力传动，泵腔与外界完全隔绝，无机封结构。避免废液泄露风险。

双泵冗余设计，保证系统连续运行。

单泵故障可区域灭菌后拆卸维修。

The pump drive adopts magnetic drive, the pump chamber is completely isolated from the outside, and there is no sealing. Avoid the risk of waste leakage.
The redundant design of double pumps ensures continuous operation of the system.
Single pump failure can be disassembled and maintained after regional sterilization

·废固处理单元 / Waste and solid treatment unit

连续截留上游进入灭活系统废液大颗粒杂质，截留精度≤1mm。

废固达到限度后进行蒸汽灭菌操作，废固灭菌后排放。

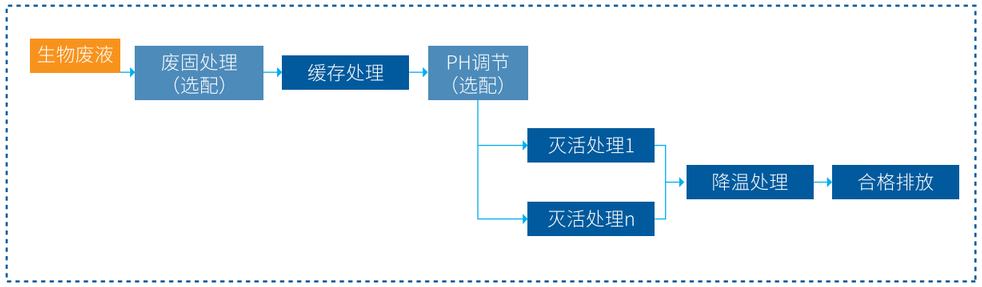
系统自动运行，无需人员对废固进行处理操作，降低人员安全风险。

Continuously intercept large particle impurities from upstream waste liquid entering the inactivation system with an interception accuracy ≤1mm.
After the waste reaches the limit, steam sterilization operation is carried out, and the waste is discharged after sterilization.
Automatic operation of the system, no personnel operation for waste solid treatment, reduce personnel safety risk.

热力灭活工艺 / Thermal Inactivation Process

二、热力批次式灭活工艺

1、工艺流程 / Process



生物废液经由废固处理单元（选配）进入缓存单元，通过泵输送至灭活单元1中，待灭活单元1达到液位设定后，废液进入灭活单元2中，灭活单元1加热至灭菌温度，维持设定时间进行灭活处理，废液灭活后进入降温单元循环降温后排放，排放后罐体内可进行CIP清洗操作处理，灭活单元1与灭活单元2批次运行，持续进行废液灭活处理。

Biological waste liquid through a solid waste processing unit (optional) enter the buffer unit, through the pump to inactivate unit 1, after being inactivated unit 1 at level set, waste liquid into the inactivated in unit 2, inactivated heating unit 1 to sterilization temperature, maintain a set time for inactivated processing, waste liquid after entering cooling unit circulation cooling discharge after inactivated, CIP cleaning operation can be carried out in the tank after discharge. Inactivated unit 1 and inactivated unit 2 run in batches to continuously inactivate the waste liquid.

2、工艺特点 / Process characteristics

- 系统工艺流程简单。
- 可选蒸汽直接喷射加热方式，热效率及热利用率高，避免传统换热器结垢带来的传热效率降低。蒸汽喷射消音装置，降低蒸汽直接加热过程中的设备震动及噪音。
- 蒸汽喷射侧壁切向与底部同时进气，增强液体搅拌，增强加热均一性。
- 灭菌罐体灭菌温度多温度点检测，充分保障罐内灭菌均一性，避免灭菌死点。
- 运行参数及数据实时记录存储。安全性高。

- The system process is simple.
- Optional direct steam injection heating method, high thermal efficiency and heat utilization rate, avoiding the reduction of heat transfer efficiency caused by scaling of traditional heat exchangers. Steam injector sound-absorbing device reduces equipment vibration and noise during direct steam heating.
- The side wall of steam injector is tangentially inhaled, which enhances liquid mixing and enhances heating evenly.
- The sterilization temperature of the sterilization tank is detected at multiple temperature points, which fully ensures the sterilization uniformity in the tank and avoids the sterilization dead point.
- Real-time recording and storage of operating parameters and data, with high security.

3、部件单元 / Component unit

·蒸汽喷射器 / Steam injector

原理：

- 蒸汽的喷射将液体从环形孔吸入、混合，再将加热后的热水喷入罐中。

特点：

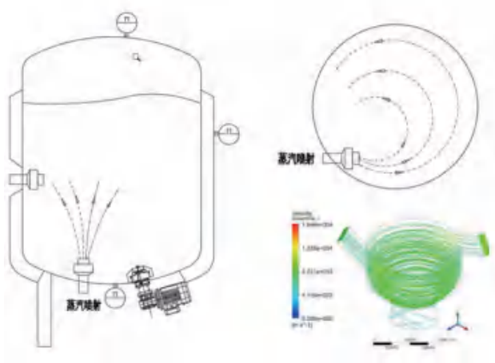
- 喷射器引起的循环确保了充分的混合，避免了温度分层差异。
- 采用消声结构，能够有效避免蒸汽喷射加热带来的噪声和振动。

Principle: The injection of steam sucks the liquid from the annular hole, mixes it, and then sprays the heated hot water into the tank.

Features: The circulation caused by the injector ensures adequate mixing and avoids temperature stratification differences.

The sound-absorbing structure can effectively avoid the noise and vibration caused by steam injection heating.

·灭活罐 / Inactivation tank



特点：

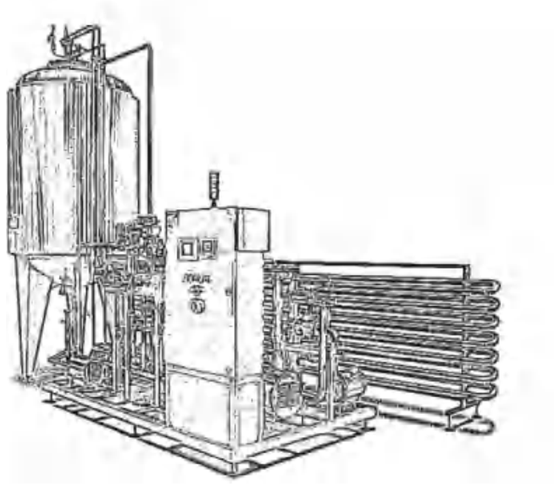
- 针对罐体容积设计的蒸汽喷射及温度检测点设计，降低温度梯度，提高温度检测均一性。
- 可选蒸汽切向喷射，推动废液搅拌。
- 罐体内胆常规材质S31603材质，表面钝化处理。
- 可选加热/冷却夹套设计。
- 可选机械搅拌或磁力搅拌。
- 配置清洗球实现CIP清洗。

Features:

- The design of steam injection and temperature detection points for the tank volume design reduces the temperature gradient and improves the uniformity of temperature detection.
- Optional steam tangential injection to promote waste liquid mixing.
- The Material of Construction for the tank inner liner is S31603, and the surface is passivated.
- Optional heating/cooling jacket design.
- Optional mechanical mixing or magnetic mixing.
- Spray ball is used in CIP cleaning.

产品选型 / Product Model

项目 Project	产能范围 Capacity	技术路线 Technology	应用 Application
小试 Small-scale production	50-300L/h	电加热/工业蒸汽加热 管式换热 Electric heating/plant steam heating Tube heat exchange	产品测试 / 产品参数研发 多品种产品小批量生产 Product testing Product parameter research and development Small-scale production of various products
中试 Pilot-scale production	300-1000L/h	电加热/工业蒸汽加热 一体机设计 Electric heating/plant steam heating All-in-one design	小批量生产 产品中试生产 Small-scale production Pilot-scale production
工业生产 Industrial production	1000-6000L/h 6000-12000L/h	工业蒸汽加热 批次多罐冗余 连续模块化组合 Plant steam heating Batch multi-tank redundancy	工业化大生产 Industrial production



客户信息表 / Customer Information Sheet

废液灭活系统信息表

V1.0

客户信息					
	客户信息				
	填写时间				
	客户联系人				
	联系方式				
1 灭活废液信息					
1-1	生物安全等级	□BSL-1	□BSL-2	□BSL-3	□BSL-4
1-2	上游生产药品品类				
1-3	废液主要成分（是否包含病原体？）				
1-4	废液PH值				
1-5	腐蚀性物质成分				
1-6	废液固体尺寸及含量				
2 运行参数					
2-1	上游生产排版情况				
2-2	废液处理重量/每天				
2-3	废液峰值流量L/h				
2-4	灭活系统运行时长/每天				
2-5	灭活时间参数 min				
2-6	灭菌温度参数 °C				
3 设备选型					
3-1	设备类型	□热力连续式	□热力批次式		
3-2	设备处理能力 L/h（预选）				
3-3	是否需要PH中和	□是	□否		
4 公用工程条件					
4-1	工业蒸汽条件	□是	□否		
4-2	工业蒸汽压力 bar				
4-3	压缩空气条件	□是	□否		
4-4	压缩空气压力 bar				
4-5	设备清洗用水类型				
4-6	动力用电条件				
4-7	灭活废液排放	□直接排放	□二次输送		
4-8	灭活废液输送扬程 m				
5 其他信息					

服务理念 / Service concept

0431-81989135

秉承“一切为客户着想，为一切客户着想，为客户着想一切”的理念，以“为客户创造价值”为己任，楚天专注于打造一流的研发、设计、销售、制造、服务团队及服务管理体系，为客户提供高效、优质的产品与服务。

项目规划支持

楚天拥有系列专业医药设计院、产品研究院，一批行业资深科研技术人员，无菌制药工艺的验证专家、教授等，为客户的项目提供科学、有效的技术规划支持。

过程保障服务

楚天推出的医药装备整体解决方案，实现药品生产过程的全自动化、无菌化，智能检测、分选，以及计算机验证保障，生产出让市场“放心”的产品。

走进园区服务

楚天作为设备供应商，不仅仅将行业法规标准融入到产品设计、制造中，还让法规标准以讲座、交流的形式走进园区，与药企的工艺、生产形成互动与融合。

设备管理咨询服务

楚天致力于满足客户效益最大化需求，提供一揽子的设备管理模式，协同药厂实现投入最小化，产出最大化。

坚持“以客户为中心”， 以匠人之心打造极致服务体验，为客户创造更多价值

34 全国 34 个省（市）

365 全年 365 天

7x24 7X24 小时服务时间

我们随时待命为客户单位设备正常运行保驾护航

+ 现场安装、调试、验收
+ 设备工艺、操作、维护等相关培训
+ 周期性的定期上门维护与回访
+ 设备各部件性能的检测与保养
+ 备品备件的及时供应
+ 产品技术升级与技术二次开发
+ 设备大修