SHE
Sanitary heat exchanger for pharmaceutical applications
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Spirax Sarco has a long history of designing and manufacturing heat exchangers. As a leading designer and supplier of clean and pure steam generators, multi-effect distillation and hygienic/pharmaceutical components, we have an intimate knowledge of the functional, documentation, certification and support requirements the Bio-pharmaceutical industry demands. With this wide experience and knowledge of the needs of sanitary systems, Spirax Sarco has designed a sanitary heat exchanger that fully meets the requirements of the Food and Drug Administration (FDA), current Good Manufacturing Practices (cGMPs), and the ASME BPE standards for bioprocessing equipment.

Key features

- All secondary fluid contact parts are manufactured from AISI 316L stainless steel
- Double tubesheet design to prevent cross-contamination and identify leaks
- Highly polished secondary fluid contact parts, with surface finish according to pharmaceutical standards (≤ 0.51 μm as standard, ≤ 0.38 μm on request)
- Single and multi-pass designs available
- Secondary stream is fully drainable and free of dead-legs
- Orbital welding throughout

Applications

- Product media temperature control
- High purity water heating and cooling (WFI)
- WFI and purified water point of use heating and cooling
- CIP fluid heating and cooling
- Re-circulated batch heating and cooling
- Condensing pure steam

Single and Multi-pass design

- Compact solutions for large heat exchange duties
- Zero dead-leg return bonnet
- 1 or 2 pass configurations
- Straight tubes for to prevent backwater and accumulation of fluid
- Easy to clean and inspect
- Fully drainable head/bonnet designed in accordance with ASME-BPE
- Optimised return bonnet bypass for drainability and thermal efficiency
Sanitary heat exchanger design

Each Sanitary heat exchanger is individually designed and tailored to meet our customer’s exact needs. Our long experience in heat exchanger design and high purity systems means that we are able to advise our customers on the best design to meet their exact requirements.

A Spirax Sarco high purity specialist will consult with you to understand exactly what your needs are, and will then work with our heat exchanger designers to arrive at the optimum design. This consultation process will also identify your testing, documentation and certification compliance requirements.

Each sanitary heat exchanger will have a double tube sheet design to ensure that in the unlikely event of a leak, cross contamination shall be prevented and it can be identified quickly and easily. If required, bellows will be incorporated into the shell design to inhibit thermal fatigue. All units will be polished and certified to meet your surface finish requirement.

The Spirax Sarco SHE can be supplied with multiple passes, has flexibility of where connections are placed and the length and diameter of connection nozzles. If required, the heat exchanger can be supplied pre-insulated complete with a stainless steel jacket.

Our gasket design is self-positioning and material selection avoids over compression and deformation whilst complying with USP class VI and US FDA requirements.

Consultation
- High purity specialists
- Identify application needs
- Identify compliance needs
- Solution agreement

Design
- Thermal and mechanical heat exchanger design specialists
- High purity compliance specialists
- Internationally recognised thermal and mechanical design platforms
- Bespoke design

Manufacturing and design standards

- ASME BPE
- ASME VIII Boiler Pressure Vessel Code
- Direttiva Europea sulle Apparecchiature a Pressione 97/23/EC
- cGMP
- FDA and USP
- ISPE Baseline Guides
Testing and inspection

Each Sanitary heat exchanger is subject to a rigorous regime of testing and inspection to ensure it meets all customer and statutory requirements. A complete set of tests and inspections are carried out on each heat exchanger to ensure that it meets these requirements and Spirax Sarco's stringent quality expectations. Additional optional testing and inspection is available to meet individual customer requirements.

Optional tests and inspection
- Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Endoscopic inspection
- Radiographic inspection
- Dye penetration inspection
- Surface roughness inspection
- Material ferrite inspection

Documentation and certification

Standard documentation
- General arrangement drawing
- Data sheet
- Installation, Operation and Maintenance Instructions
- Hydrostatic report and CE conformity declaration
- Weld documentation
- Material certificates
- Pickling, passivation and surface finish procedures certificates

Packaging

All units are packed and shipped in a controlled manner including cleaning, passivation, purified water rinsing, air dried and capped. Options including pressurising with inert gas for transportation and storage.
<table>
<thead>
<tr>
<th>Key features</th>
<th>Key benefit</th>
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<tbody>
<tr>
<td>Double tube sheet construction</td>
<td>Double tubesheet design to prevent cross-contamination and quick leaks identification.</td>
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<td>Self-draining</td>
<td>No areas where media can accumulate and cause hold-up.</td>
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<td>Stringent testing and inspection</td>
<td>Full range of standard and optional quality and performance tests.</td>
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<td></td>
<td>‘Factory Acceptance Test’ and ‘Site Acceptance Test’ fully performed.</td>
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<td>Full validation documentation and certification service.</td>
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<td>Modular heat exchanger packages</td>
<td>Pre-engineered and assembled heat exchange system with all the necessary control and ancillary equipment.</td>
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<td>Minimal installation and onsite commissioning.</td>
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<td>Part of a dedicated high purity range from Spirax Sarco</td>
<td>Provides customers with a single source of supply for all their high purity needs.</td>
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<td>Steam industry leader with vast application knowledge and understanding of heat transfer technology and steam and utility controls</td>
<td>Steam specialists in both the high purity and plant side of your business.</td>
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<td>Global company with worldwide local expertise and support.</td>
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<td>Compliance to all international pharmacopeias and industrial standards</td>
<td>Heat exchangers designed to meet all international pharmacopeias and industrial design standards.</td>
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Global coverage