BioProcess™ Modular System

BioProcess Modular systems are automated liquid chromatography systems, built for process scale-up and large-scale biopharmaceutical manufacturing (Fig 1). The proven design, based on the successful ÄKTAprocess™ system, has been verified during development and can be configured to meet specific process demands. BioProcess Modular systems are the obvious choice when scaling up processes developed on smaller ÄKTApilot™ and ÄKTAprocess systems.

- Versatile user-configuration with UNICORN™ control software
- Post-purchase configuration increasing usability and lifespan
- Traceable USP Class VI materials
- Intelligent packing of AxiChrom™ columns
- Full regulatory documentation and services

**Versatile user-configuration**

BioProcess Modular systems provide thousands of configuration possibilities (Fig 2). The systems are available in two flow-rate ranges that extend up to 10,000 l/h for large volume manufacturing. The compact design with a built-in computer, allows the system to fit neatly into a plant with minimum floor-space utilization.

BioProcess Modular systems are constructed in high-grade, electropolished stainless steel. Stainless steel systems are recommended for use in applications where salt concentrations are low and pH is above 5. If process conditions include high salt or low pH, it is essential that the system is thoroughly cleaned after use.

BioProcess Modular systems can be configured to develop gradients at any flow rate with feedback loop technology. This ensures thorough mixing of liquids/solvents without air bubbles, so that even challenging gradients can be created with 98% accuracy (Fig 3).

The built-in computer, with UNICORN software, allows stand-alone operation or integration into any plant-wide control system. Additional configurations include, for example, the choice of extra inlets and outlets, the type and quantity of selected monitors, and isocratic versus gradient functionality. BioProcess Modular systems can also be delivered with a Profibus gateway (PI-960) instead of UNICORN, thereby enabling the system to be fully controlled by a local control system.
Post-installation modification to increase usability and lifespan

Owing to the flexibility of the design, post-installation changes such as the addition of valves, filters, and pumps are possible. This allows a system to be reassigned to another process with different requirements, thereby increasing the versatility and working life. Upgrades can also be installed to increase the lifespan of the system, which also protects the investment value of the system.
with control systems within the plant via Object Linking and Embedding (OLE) for Process Control (OPC). OPC supports application areas such as data access for real-time values and security control to protect sensitive information [see Data file 11-0004-15].

**Intelligent packing of AxiChrom columns**

BioProcess Modular systems have been developed to function with intelligent packing of AxiChrom columns. In addition to saving time, intelligent packing ensures consistent reproducibility of results with scalability, whether upscaling or downscaling, throughout the AxiChrom column family. Parameters used in the intelligent packing procedure are set using a wizard in UNICORN. UNICORN controls the packing and testing, with continual monitoring of the pressure to detect when the bed is settled, through to final compression of the bed.

**Full regulatory documentation and services**

Process safety is an integral part of BioProcess Modular systems. We provide documentation to verify that the materials used to build the system are all USP Class VI and are traceable back to their original production batches.

Regulatory authorities demand that pharmaceutical manufacturers validate equipment before use in production. Fast Trak Validation™ offers a comprehensive range of specialist services to support the development and production of biopharmaceuticals. A range of validation documentation, such as Installation and Operation Qualification (IQ/OQ) documentation, is available. In addition to producing the documentation, GE Healthcare also offers its expertise to perform the actual qualification of the system on-site.

Fast Trak Validation also offers Standard Operating Procedures (SOPs) that describe how to use and maintain BioProcess Modular systems during regular operation. SOPs can be specifically written for systems controlled by UNICORN, while other SOPs are required for procedures used in GMP environments.

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### System specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>System flow rate</td>
<td>500–5000 l/h</td>
</tr>
<tr>
<td></td>
<td>1000–10 000 l/h</td>
</tr>
<tr>
<td>Piping diameter</td>
<td>1 ½” o.d. (34.8 mm i.d.) stainless steel (SS)</td>
</tr>
<tr>
<td></td>
<td>2” o.d. (47.5 mm i.d.) SS</td>
</tr>
<tr>
<td>UV wavelength range</td>
<td>Single (280 nm) or multiple wavelengths</td>
</tr>
<tr>
<td>pH range</td>
<td>0–14 (spec. valid between 2 and 12)</td>
</tr>
<tr>
<td>Conductivity range</td>
<td>1 to 200 mS/cm</td>
</tr>
<tr>
<td>Ingress protection</td>
<td>NEMA 4X / IP 56 electrical cabinet</td>
</tr>
<tr>
<td>Electrical standards</td>
<td>UL 508A, EN 61010-1</td>
</tr>
<tr>
<td>Skid size [W × H × D]</td>
<td>2378 × 2633 × 1118 mm</td>
</tr>
<tr>
<td>(D = 3000 mm if including monitor</td>
<td></td>
</tr>
<tr>
<td>and keyboard)</td>
<td></td>
</tr>
<tr>
<td>Process temperature</td>
<td>4°C to 80°C</td>
</tr>
<tr>
<td>Surrounding temperature</td>
<td>2°C to 30°C</td>
</tr>
<tr>
<td>Maximum operating pressure at</td>
<td></td>
</tr>
<tr>
<td>operating temperature:</td>
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</tr>
<tr>
<td>4°C to 40°C</td>
<td>5 bar</td>
</tr>
<tr>
<td>40°C to 60°C</td>
<td>3 bar</td>
</tr>
<tr>
<td>60°C to 80°C</td>
<td>1 bar</td>
</tr>
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