



FDA-COMPLIANT, CORROSION-RESISTANT VALVES & PUMPS

THE PERFECT SOLUTION FOR THE PHARMACEUTICAL INDUSTRY,
WHERE PRECISION AND PURITY MEET INNOVATION



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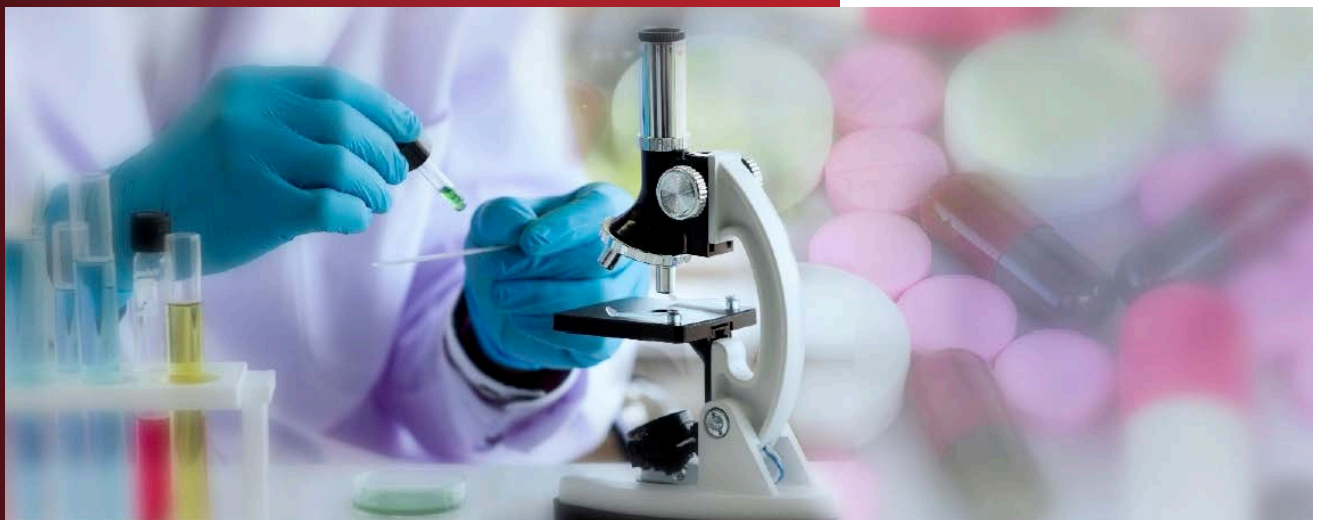
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INTRODUCTION

Active Pharmaceutical Ingredients (APIs) are the heart of modern medicine. They are the chemical substances in drugs that have a therapeutic effect on the body. APIs are produced through complex chemical and biotechnological processes and are subject to strict quality controls to ensure their safety and efficiency. Richter plays a crucial role in API production by providing high-performance, PFA-lined pumps and valves.

API PRODUCTION: AN OVERVIEW

APIs can be of natural origin, such as plant extracts or enzymes, or produced through chemical synthesis and biotechnological processes. During drug development, APIs are synthesized, isolated, and purified to achieve the desired pharmacological effect. APIs are often combined with inactive ingredients or excipients to formulate the final drug, which comes in various dosage forms such as tablets, capsules, or injections.





SOLUTIONS

RELIABLE SOLUTIONS FOR API PRODUCTION

Richter is a leading supplier of PFA-lined pumps and valves widely used in the pharmaceutical industry. These products are specifically designed for demanding applications involving aggressive chemicals and high purity requirements.

Reactors and Synthesis Processes:

Richter's pumps and valves are used around reactors to safely handle corrosive and toxic liquids. This is particularly important in API synthesis, where corrosive chemicals are used.

Cleaning and Sterilization:

Richter products are ideally suited for Clean-in-Place (CIP) processes, essential for cleaning and sterilizing production equipment. Since these processes often involve explosive solvents an ATEX Ex-zone-compliant design is frequently required. Richter provides an option for a conductive liner that is ATEX EZ-zone compliant. This conductive lining is also available with FDA compliance.

Transport and Storage:

The transport and storage systems of raw materials and intermediates of APIs require reliable and corrosion-resistant pumps and valves. Richter products offer the necessary safety, efficiency, and durability.

BENEFITS

WHY RICHTER PRODUCTS ARE THE FIRST CHOICE FOR THE PHARMACEUTICAL INDUSTRY:

- _ **Corrosion Resistance:** The PFA lining of the pumps and valves **is universally resistant to corrosive substances**, especially the chemicals used in API production.
- _ **Reliability and Durability:** Richter products are known for their **high reliability and long service life**, making them ideal for use in critical pharmaceutical processes.
- _ **Safety:** The products are designed to meet the highest safety standards, which is particularly important **when handling toxic and hazardous substances. The conductivity of the pumps and valves also ensures safe use in explosive areas (Ex-zones)**, especially when using solvents in CIP processes.
- _ **FDA Compliance:** The products meet the stringent standards of the US Food and Drug Administration (FDA) for pure and antistatic PFA. This means they **can be safely used in the manufacture of pharmaceutical products** intended for human consumption.
- _ **Oil and Grease-Free Assembly:** The assembly and packaging of the products are carried out according **to a special cleaning specification developed in collaboration with customers from the pharmaceutical industry. This eliminates any contamination with grease and oils.**
- _ **Low Dead Space Product Design:** The products are designed with minimal dead space where residues could accumulate. They are also optionally available in a completely dead space-free design, which further facilitates cleaning and minimizes the risk of contamination
- _ **Cost Savings:** Thanks to the high durability and reliability of the products, the lowest life cycle costs are incurred. Every avoided replacement of failed valves and pumps saves time and money.
- _ **Pure PFA or Antistatic PFA:** The products are available in variants made of pure PFA or antistatic PFA. Pure PFA is always FDA compliant. Antistatic PFA is FDA compliant depending on the actual material blend. Both pure and conductive PFA offer excellent chemical resistance, while antistatic PFA additionally prevents electrostatic charges on the wetted contact surfaces. This is particularly important for safety during CIP cleaning with solvents.
- _ **Simplified and Fast Cleaning and Disassembly:** The products are designed to be quickly disassembled and easily cleaned. This saves time and reduces downtime in production.
- _ **Stainless Steel Housing:** In addition to the standard design with ductile iron housings, stainless steel housings are optionally available for certain models including diaphragm valves, ball valves, and sampling valves. This offers additional advantages in cleaning the housing.
- _ **TA Luft Certification:** The products are certified according to the latest TA Luft standards of 2021 (ISO 15848). This certification confirms that the products meet the stringent German emission requirements, underscoring their environmental friendliness and safety.

PRODUCTS

PRODUCT RANGE FOR PHARMACEUTICAL INDUSTRY:

1. Heavy Duty Ball Valves (KN, KNA):

These ball valves are known for their low dead space ball shaft, which allows for better disassembly and cleaning. They are ideal for use in API synthesis processes where high purity is required.

_ **Features:** Low dead space design, maintenance-free due to self-adjusting switch stem sealing, easiest disassembly with ceramic ball



2. Butterfly Valves (NKL, NKS):

These butterfly valves are known for their reliability and durability. They are a good option for larger pipe sizes compared to ball valves, especially for shut-off and control tasks.

_ **Features:** Corrosion resistance, reliability, and durability



3. Bellows-Sealed Control Valves (RSS):

These valves offer precise control and regulation of liquids and gases in API production processes. They are designed with low dead space and are easy to maintain and clean due to the top-entry design. As option a completely dead space free design is available.

_ **Features:** These valves are all FDA compliant and available with either standard or conductive lining. They are standardly lined with at least 5 mm thick PFA and offer control ranges starting from 0.01 m³/h



4. Safety Valves (KSE):

KSE3.0 of the latest generation. These valves are designed to meet the highest safety standards and are used in critical API production processes to prevent overpressure situations.

_ **Features:** High reliability, safety, high discharge capacity, FDA certification



5. Sight Glass Fittings (PSG):

These fittings allow visual monitoring of liquids in API production processes and are lined with PFA to ensure high chemical resistance.

_ **Features:** Conductive FDA certification, easy cleaning.



6. Diaphragm Valves (MV):

Stuffing box-free shut-off valve. Ideal for high purity requirements and residual drainability, as the valve is designed to be dead space-free and completely drainable at certain installation angles.

_ **Features:** Dead space-free design, residual drainability, easiest cleaning



PRODUCTS

7. Pumps (RMI/RMA, MNK/A, SCK):

Richter pumps are known for their high performance and reliability and are used in various API production processes. They are lined with PFA to ensure the highest chemical resistance. Available with optional conductive lining. Both magnetic drive and mechanical seal versions available. Even vertical installation for automatic residual drainage possible.

Features: Longest service life and lowest life cycle costs. Oil and grease-free assembly, FDA certification for pure PFA and conductive PFA lining



COMPLETE SOLUTIONS

Richter valves and pumps are also supplied as driven and automated complete units; including assembly, piping, wiring, testing, and certification of accessories.



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