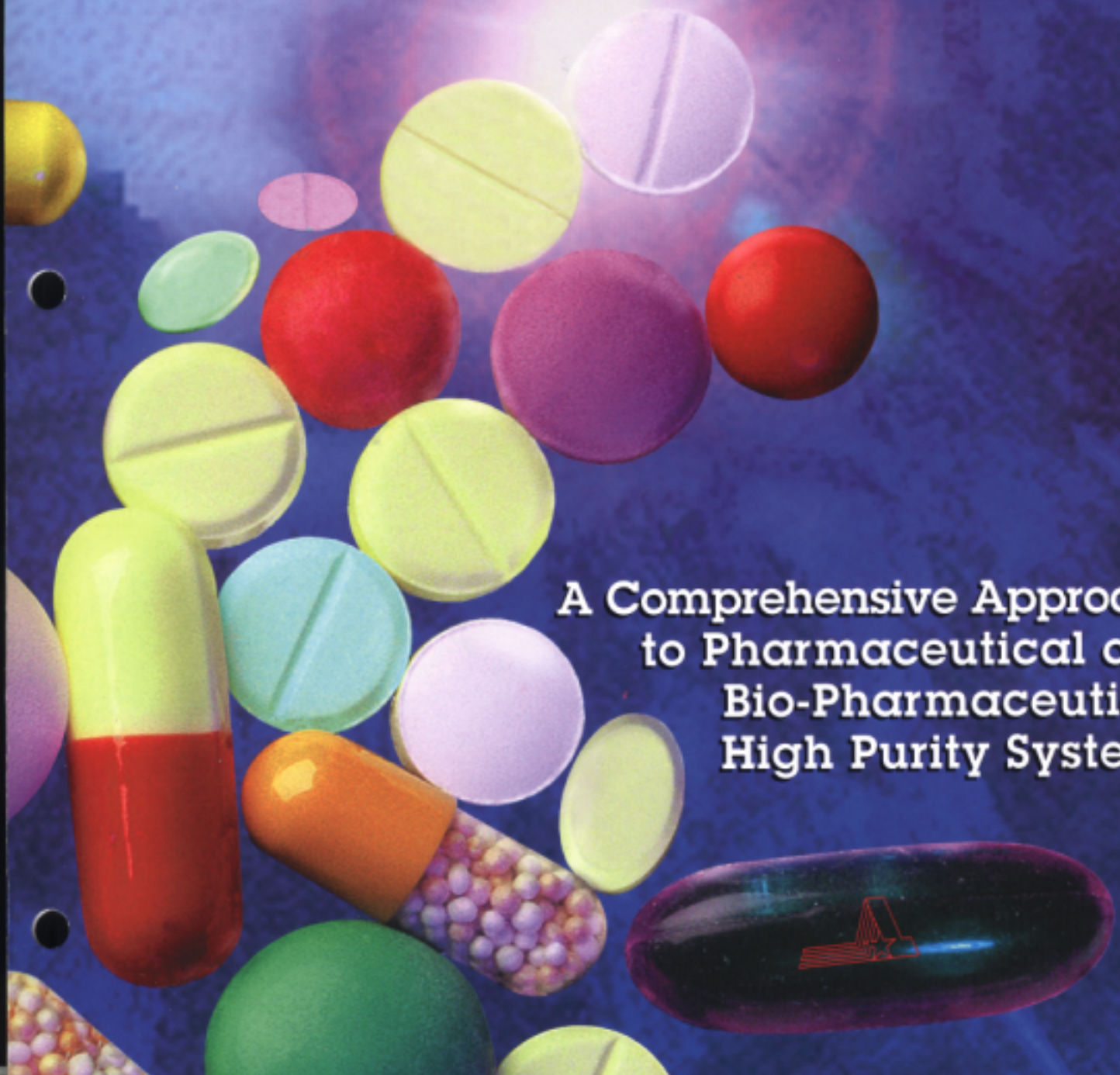
ASAHI/AMERICA

Thermoplastic Pipe, Valves, Fittings, and Flow Meters



A Comprehensive Approach to Pharmaceutical and Bio-Pharmaceutical High Purity Systems

HIGH PURITY: PURE AND SIMPLE

Biotechnology is changing the pharmaceutical marketplace. Ground-breaking technology provides new methods for producing pharmaceutical products. These innovations require the need for cleaner, better, faster-built, and longer running operations without the need of system shutdowns. The use of thermoplastic materials in production systems is the latest advance in reducing costs, with the added benefits of improving operational efficiencies and system purity. Asahi/America is pioneering the way for the industry to take advantage of the benefits of these materials.

Asahi/America's immediate focus is demonstrating to the pharmaceutical and bio-pharmaceutical industries many of the advantages that thermoplastic piping systems (pipe, fittings, valves, and instrumentation) have over metal systems for high purity applications. We are working side-by-side with a number of manufacturers and consultants in the industry to provide systems that improve new, as well as existing operations. Our systems are designed around the stringent requirements defined by FDA guidelines and listed in all current codes. Asahi/America offers more than products. We are experienced with system design, application expertise, installation planning, and regulatory adherence.

Asahi/America is the producer of flow monitoring products. The Agru company of Austria is the producer of Purad and PolyPure pipe and fittings. Together, we offer a comprehensive approach to high purity systems.

A STRATEGIC APPROACH TO HIGH PURITY SYSTEMS

Asahi/America and Agru offer superior quality, unpigmented, natural polypropylene (PolyPure), and PVDF (Purad) products for many applications in research and development and manufacturing. PolyPure and Purad pipe, fittings, valves and instrumentation are particularly well suited for *high purity water systems*. For a Water For Injection (WFI), installation, Purad may readily be substituted for 316L stainless steel. Since it may be steam sterilized, Purad is also a good choice for solution preparations and transfers. For Purified Water, cost-effective, natural Polypro is the material of choice. Both PolyPure and Purad have undergone extensive testing for extractable levels, and the FDA has approved these materials for food and pharmaceutical applications.

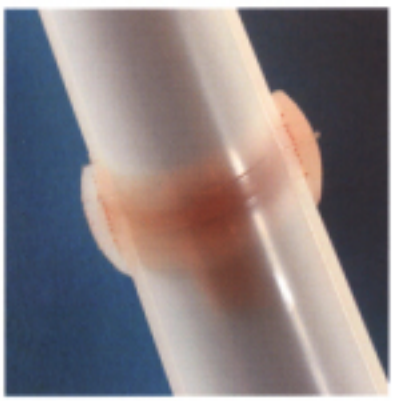
PLANNED QUALITY CONTROL FROM MANUFACTURING TO SYSTEM VALIDATION

Asahi/America uses a regulatory approach in both the manufacturing and technical support of its High Purity products. All components are produced in several clean room environments according to ISO9001 procedures. A rigorous quality control program assures that the customer shall receive products as specified and packaged so that they are 100% contamination free.

Asahi/America issues a quality assurance certificate for each batch of components, which we will furnish to you upon request.

All Asahi/America and Agru products come with installation, engineering and validation support. The key to validation is documentation: Asahi/America supplies all the information required by the regulatory agencies for pharmaceutical and bio-pharmaceutical applications.

The documentation is in a format that readily translates to protocols for Installation Qualification (IQ) and Operational Qualification (OQ). Even if the client



Welding Systems offer smooth internal surfaces for maximum purity performance. No internal beads during welding provide a system ideal for demanding Pure water and WFI applications.

The Purad system makes the transition from Stainless Steel to High Purity PVDF seamless. Sanitary Transition fittings mate to metal systems allowing Purad to be used in new and existing systems, making thermoplastic ideal for all future additions, modifications and improvements.

uses a different protocol format, the information is easily inserted. For greater convenience, an electronic version will be available.

ELIMINATION OF HISTORIC SYSTEM WORRIES

Here are just a few of the notable advantages of employing our thermoplastic piping systems: material and installation costs are lower than with conventional metal systems; chemical resistance is extremely high; rouging and associated metal contamination problems are nonexistent; and borescoping and passivation are not required. In addition, we manufacture all materials with smooth surfaces to meet or exceed the standard for Mechanical and Electropolished Stainless Steel. These smooth surfaces are unfavorable for the proliferation of microorganisms.

COMPREHENSIVE PRODUCT OFFERING

Asahi/America offers PolyPure and Purad products in sizes to fit your needs. For both large and small systems, Purad is available in a complete offering of 1/2" to 12". PolyPure may be obtained in sizes of 1/2" to 4". Both PolyPure and Purad fittings and Valves are also available in zero dead leg configurations.

In addition to piping, fittings and valves, Asahi/America's Vortex Flow Meter is ideal for sanitary pharmaceutical and bio-pharmaceutical operations. The instrument has no moving parts and is crevice free. It may be steam-sterilized and can be installed in Purified Water, Water For Injection, and Solution Preparation Systems.

Asahi/America also offers the Air-Pro system of piping and fittings products for pharmaceutical compressed air applications and special gasses systems. If you require sanitary piping and distribution of air, nitrogen, carbon dioxide and other inert gases, Air-Pro offers a more cost-effective system in comparison to Stainless Steel piping systems.

With over 15 years experience in ultra high purity thermoplastic piping, Asahi/America is capable of supplying trouble-free systems of any size, as seen in this Purad installation of PVDF piping.

PRACTICAL JOINING TECHNOLOGY APPROPRIATE FOR EACH APPLICATION

For each type of installation Asahi/America will provide the appropriate type of joining equipment. Joining technology is available in beadless joining, automated IR, butt fusion, and socket fusion. The HPF system is the only method on the market that provides practical fusion with a smooth inner surface. Welds can be done quickly in almost any location. HPF equipment is completely portable making installations, tie-ins, and additions easier to conduct than ever before.

PRODUCT STRATEGY FOR EACH APPLICATION

- For a Purified Water System, PolyPure is recommended.
- For a Water for Injection System, Purad is the best choice because of its high temp and pressure capability.
- For Solution Preparation and Transfer, again, Purad is the practical choice.
- For Pharmaceutical Compressed Air and Special Gasses, Air-Pro is the recommendation.
- For all systems, contact our high purity teams for technical specifications and engineering assistance.

The Purad PVDF System is available from 1/2" to 12" with all the required sanitary components necessary for an ultra pure installation.

The HPF Welding System is unique in its ability to conduct ultra pure welds in tight locations, such as in pipe racks and under sub-floors.