

# Ten Tips for Single Use Pharmaceutical Tubing Selection

Tubing used in pharmaceutical and biotech applications has particular requirements. Among them are the ability to withstand sterilization processes, the delivery of favorable test results regarding extractable substances, and the absence of animal-derived ingredients. These industries also have tubing needs involving flexibility, performance, and cost that are common to many applications.

How do you know if one type of tubing will function better than another in your specific application?

Research, investigate, ask questions, and consider the following ten points.



**1. Ingredients** Today's pharmaceutical and biopharmaceutical manufacturers have found that the best way to eradicate animal ingredients and their possible effects on finished products is to start with processing components that do not contain any animal ingredients or animal-derived ingredients. Another substance that can be troublesome is silicone oils. The oils can react with other components and leave a residue in the final product. Check with your supplier to find out if your tubing contains animal-derived ingredients or other undesirable elements.

**2. Cleanliness** Although tubing is sterilized prior to use, it makes sense to start with the cleanest possible product. Learn about the conditions in which the tubing is manufactured. Is it produced in a clean room? If so, what level (ISO 6, 7, 8)? How is it handled and stored after manufacture? Has it been tested for contaminants by an independent laboratory?

**3. Association standards** Does the tubing you're considering for your single use application need to meet USP, FDA, ISO, European Pharmacopoeia, or other standards? Some applications will demand that the tubing itself meet certain standards, while others will be satisfied when the tubing ingredients (the raw materials plus additives) meet those guidelines.

**4. Sterilization** What methods can be used to sterilize the tubing? Autoclave (steam sterilization), EtO (ethylene oxide) gas treatment, gamma irradiation, something else? These questions should be researched or posed to suppliers to help you make an informed decision. Another point to consider is whether you will receive tubing that is pre-sterilized or if you will handle that process. If you'll be ordering pre-sterilized tubing, you need to make sure that the supplier's process has been validated to the degree of sterilization necessary.

**5. Absorption, adsorption, and permeability** Absorption (the penetration into the mass of one substance by another), adsorption (when molecules of a substance collect on the surface of another), and permeation (the diffusion of one substance through another substance) are details to examine when evaluating tubing. Materials differ greatly in how they contribute to these factors, and the fluids or gases for which the tubing is intended need to be considered. TPE (thermoplastic elastomer) tubing, for example, is

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much less permeable than typical silicone tubing. How does the tubing material you're considering perform when it comes to these elements?

**6. Validations and extractables** Tubing materials like platinum-cured silicone are inherently purer than peroxide-cured silicone and offer fewer extractables (substances that can be drawn out of a material). Testing should be performed to confirm that any extractables or substances in the tubing's makeup do not adversely affect the product flowing through it and vice versa. Has the tubing you're considering undergone the necessary tests to ensure its suitability for your application? Was it third party tested, or will you rely on test results conducted in-house by the manufacturer? Without validated test certifications, you may put your products, as well as lives, at risk.

**7. Sealing and welding capabilities** Pharmaceutical and biopharmaceutical manufacturing often involves the retention of batch samples, which are specimens of the drug or substance being produced. These liquid samples are frequently stored in small bags with tubing attached or within a section of the tubing itself. This tubing must be permanently sealed without breaking sterility, preferably inner wall to inner wall using heat and compression, to prevent spillage and contamination. Tubing materials such as silicone cannot be heat sealed and require the use of mechanically applied fittings or connectors to stop flow or to join two pieces of tubing together. Other materials like thermoplastic elastomers work very well in typical heat sealing processes. Tube welding – a procedure where two open ends of tubing are thermally and permanently connected to each other – is another common function often employed in pharmaceutical and biopharmaceutical manufacturing. As with heat sealing, silicone cannot be welded but TPE's can.



**8. Multiple tubing materials** Many pharmaceutical manufacturers use a peristaltic pump and silicone tubing in their processes. But as noted above, tubing that can be heat sealed and welded is often needed at some point along the fluid path. Some manufacturers use one material for certain sections of their process, connect a piece of silicone tubing for the peristaltic pump section, and then return to the first tubing material. This setup involves multiple barbed fittings, cable ties, and the potential for leaks and contamination, as well as human error. Situations have even occurred where an operator has installed

the wrong section of tubing in a pump, resulting in lost pharmaceutical product, equipment replacement, and hours of time and labor. Tubing materials such as TPE's meet the requirements for a flexible, high purity, peristaltic pump tubing that may be welded and sealed, thereby eliminating multiple materials. Like silicone, certain TPE's can be molded into connections such as Y's (wyes) and T's (tees), further reducing the need for fittings and the possibility of leaks. Consider whether a single tubing material can be used in your application.

**9. Peristaltic pump life** This involves two points: how long the tubing lasts in the pump and how long the pump itself lasts. Peristaltic pump tubing needs to withstand repeated compression and release without losing its shape, as oval or distorted tubing may not produce an even flow. The tubing also needs to perform consistently for pumping campaigns that can last many hours, so durability is a must. Related to that is how the tubing affects the pump. If the tubing is too hard or too soft, it may wear pump parts more quickly. Typically the harder the pump has to work, the shorter its lifespan. Some tubing is designed specifically for pump use, while others are made for a variety of uses. These factors should all be taken into account during the tubing selection process.

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**10. Cost** When tubing is just one part of a fluid system, it is sometimes an afterthought. This is unfortunate because savings can be realized not only in the acquisition cost but in terms of labor and inventory as well. As noted in Tip 8, "Multiple tubing materials," using one type of tubing has many benefits. It can reduce the initial purchase cost because your buying power is improved. For instance, your cost to purchase 5,000 feet of a single material may be less than buying 2,500 feet of two different materials. Using a single tubing material also decreases the cost of carrying inventory (stocking one tubing type verses two). Another benefit is lower labor expenses. There are fewer connections to make, which means fewer fittings and tie wraps to purchase, too. One tubing material also saves engineering expenses, because there's less design work involved.

**Bonus tip** AdvantaPure offers both silicone and TPE tubing for single use pharmaceutical applications. AdvantaFlex® biopharmaceutical grade TPE was developed specifically for the pharmaceutical and biologics industries. AdvantaFlex is flexible, sterilizable, moldable, heat sealable, and weldable. It contains no animal-derived ingredients or

silicone oils. AdvantaFlex maintains its physical properties following sterilization processes, resists kinking, and remains translucent for visible product flow. These unique properties help AdvantaFlex outperform and outlast similar tubing in peristaltic pumps. AdvantaFlex can, in fact, last up to ten times longer than other tubing. Learn more at [www.advantapure.com/advantaflex.htm](http://www.advantapure.com/advantaflex.htm).

Low volatile grade, platinum-cured silicone tubing is inert, extremely flexible, and offers a wide temperature range (-100°F to 400°F, -73°C to 204°C). Called APST, the tubing has undergone extensive physical, chemical, and biological testing and meets USP Class VI, FDA CFR 177.2600, ISO 10993, European Pharmacopoeia 3.1.9, and 3-A standards. Find out more at [www.advantapure.com/apst-silicone-tubing.htm](http://www.advantapure.com/apst-silicone-tubing.htm). APSPG pump grade silicone tubing is also available.



#### *About AdvantaPure and NewAge® Industries*

The AdvantaPure division of NewAge Industries is ISO 9001:2008 certified and specializes in high purity tubing, hose, single use systems, manifolds, and other molded components for the pharmaceutical, biologics, food, beverage, and cosmetic industries. All products are manufactured, stored, and shipped using the cleanest methods possible to ensure unsurpassed product purity.

In business since 1954, NewAge Industries ([www.newageindustries.com](http://www.newageindustries.com)) manufactures and fabricates thermoplastic and thermoset tubing in both reinforced and unreinforced styles. The company offers one of the broadest product lines of tubing and fittings in the U.S., provides extensive custom extrusion and fabrication capabilities, and services customers worldwide. RFID systems, including gamma-irradiatable tags and labels, are offered by NewAge's Verigenics™ division ([www.verigenics.com](http://www.verigenics.com)). NewAge initiated an ESOP (Employee Stock Ownership Plan) in 2006 for the benefit of both its employees and its customers.

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