OmniTop Sample Tubes® with OctoCap™

Novel Devices Designed to Simplify Bioprocess Fluid Sampling & Operations

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The conical tube is one of the most universally accepted and commonly used products for collecting samples and can be found in virtually any laboratory environment. Bioprocess production requires frequent in-process sampling to confirm product integrity and conformance. To achieve this, an accurate sample must be taken that is a complete representation of the product being manufactured. Contaminates can cause false positives that could lead to poor decisions about product conformance based on these inaccurate results.

The current practice for taking samples using a conical tube is to open the top cap and expose the tube and the product to the outside environment, or to use an isolator or environmentally controlled cabinet while sampling. This exposure of the tube and the open sampling process can lead to product contamination. The use of an isolator, albeit safe, is both time consuming and cost prohibitive. This article will explain how the advancements in conical tube cap design have made OmniTop a critical component in upstream and downstream bioprocess applications, saving both time and money.

Closed System Sampling with a Conical Tube

P AW BioScience developed OmniTop Sample Tubes®, a platform of conical tubes with uniquely designed caps to achieve closed system sampling and fluid transfers. The rigid wall of the conical tube makes an ideal collection and transfer vessel. The standard OmniTop design is a simple ready to use device. By connecting a 50mL Syringe to the 0.2µm vent filter, the operator can easily pull back on the syringe creating a vacuum in the OmniTop forcing the sample to be drawn.

PAW BioScience designed a new generation of caps for the Omnitop product line. The eight sided caps, referred to as OctoCaps™, are one-piece injection molded caps configured to fit various sized conical tube volumes. The simple molded design eliminates the need for far more exotic and expensive closure systems currently being offered by other suppliers. OctoCap™ is designed with two ⅛" hose barb connections to allow for filter and inlet connections.

CAP Design: The Key to Maintaining Functionality and Sterility

The OctoCaps™ were designed using a plug seal that seats itself inside the conical tube opening. The plug seal is achieved by an interference fit of the outside surface of the plug seal feature and the inside surface of the conical tube neck.

Additionally, the cap is designed with an octagonal outer surface feature that allows for the easy use of a torque wrench. During assembly, NIST traceable torque wrenches provide a validatable means to guarantee perfect assembly of each Omnitop Sample Tube® device. Testing has shown that OmniTop with OctoCap™ are leak-proof up to 10psig.

OctoCaps™ are designed to fit both 15mL and 50mL Polypropylene tubes as well as 50mL glass tubes. The glass tube is designed to seal using a flat silicone gasket. Glass conical tubes are used for long term storage of final product for stability testing.

Application 1: OmniTop simplifies Cell Inoculation

Maintaining sterility throughout every step of production is a critical aspect of Bioprocess Production. Any fluid addition to the bioreactor is an opportunity for potential contamination. In order to reduce the risk of contamination good aseptic technique is required and ideally all connections are made in a closed system environment. One of the first steps in a bioprocess production is the cell inoculation. The OmniTop is a perfect vessel for this small volume addition. OmniTops can be sterile

connected to the bioreactor with a commonly used tube welder. After connecting a syringe to the 0.2µm filter, air can be driven into the OmniTop which forces fluid into the bioreactor via the dip tube. Because OmniTop is a closed system it has greatly simplified any small volume addition to a bioreactor and is now being used for many upstream Bioprocess applications.

Application 2: Moving Beyond the Isolator for In-Process Sampling

It is common practice in the Biotechnology and Pharmaceutical industries to use isolator or biological safety cabinets to take samples. Isolators are used to separate human manipulation and the potential for contamination from the product being manufactured.

Isolators require continual environmental monitoring and a strict cleaning regimen to maintain sterility. Sampling using an isolator increases the cost of sampling and time consuming to the production timeline.

Again, because OmniTop is a closed system sampling method the sampling method is able to move this very costly and time consuming sampling operation outside of the isolator while still maintaining product and sample integrity with OmniTop.

Application 3: Single Point Connection - Multi-Day Sampling of bulk final product

OmniTops are supplied in custom configurations including multi-tube manifolds. Custom manifolds are designed with any variation of conical tubes to allow the greatest degree of flexibility in sampling design. With a single point connection, daily or multi-day samples can be taken eliminating the risk of making multiple connections to the process.

When taking multi-day samples, it is critically important that the line between your sample site and your vessel not have hold up from the day's previous sample. The holdup volume in this transfer line will not be a representative sample of the process. The OmniTop is designed to have the ability to clean the connection line after a sample is drawn. Once the sample is taken by pulling a vacuum in the OmniTop, the syringe can then be removed and drawn back with air. The syringe will then be used to push air into the OmniTop through the 0.2µm filter to push the remaining fluid in the sample line back to your vessel. Additionally, a waste bottle can be included with the manifold to allow pre-sample flushing.

Summary

OmniTop Sample Tubes® with OctoCaps™ are a convenient BioProcess solution that can be used to obtain fluid samples and perform small volume transfers. OmniTops are available with or without internal dip-tubes to facilitate removal of the fluid inside. OmniTop Sample Tubes® are available in a wide variety of standard configurations or they can be customized to suit your specific applications.