CRITICAL PROCESS FILTRATION, INC.

Application Summary

Particle Removal in Drug Production

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There are many reasons to remove larger particles, those 1 micron or larger, in the chemicals used in small molecule drug production. Because the manufacturing of almost all small molecule drugs is done using chemical processing, removing unwanted particles will improve process efficiency and protect the quality of the products created by the processes.

Each chemical component or raw material used in production has its own unique characteristics. Filters are used to assure that the ingredients are free of harmful particulates and must be chosen based on those characteristics.

Particle removal, also called clarification and prefiltration, can mean many things within different processes. In some cases it may be removing larger particles (larger than 5 µm). In other operations the removal of particles larger than 1µm might be called for. In still others, clarification and prefiltration may be defined as removing particles and some bacteria.

For purposes of this summary we will focus on particle removal.

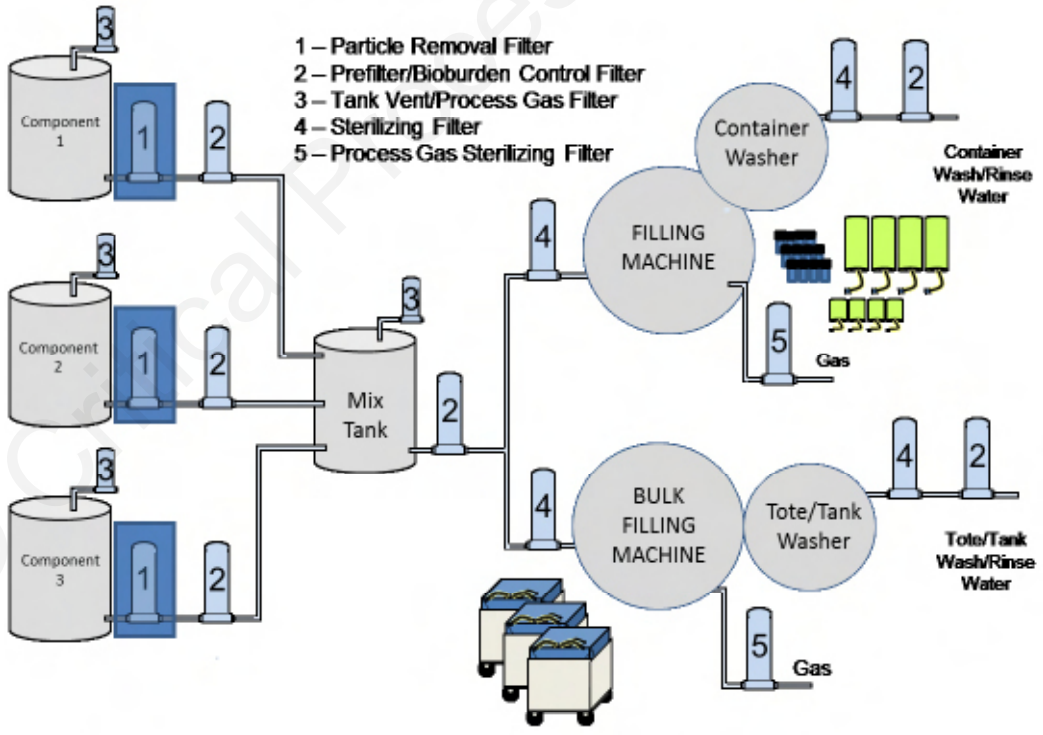

Figure 1: Particle Filters in Small Molecule Drug Production

The filters highlighted in Figure 1 are one example. There are many possible filter system configurations in production. This simplified version shows one location for particle removal, just as chemical components are being supplied to the manufacturing process.

Particles can certainly be introduced to the process with ingredients from outside sources. But if a component has been mixed using powdered ingredients, for example, undissolved powder and impurities in the solid ingredients can be carried into the process. Similarly, the processes themselves can generate particles either because of chemical reactions or due to normal wear and tear on system components such as pumps and valves.

Removing these particles, no matter the source, is a critical process that improves protects downstream process efficiency and protects the quality of your final product.

Choosing the Right Filters

Almost all particle removal filtration applications are done using depth filtration media. Cartridge filters use two forms of depth media. The standard depth filter is a self-supporting tube made using a polymer, most often polypropylene. The tube is formed using the melt-blown or nano-spun process.

The other form of cartridge depth filter uses pleated flat sheet media, most often made with polypropylene or fiberglass. Polypropylene is the most widely used material for water and chemical filtration, but fiberglass has better filter efficiency and generally allows higher flows and throughput than polypropylene in prefiltration applications.

Standard depth filters will capture a range of particle sizes through the thickness of the media. Pleated media filters have the advantage of a large surface area that can hold a higher quantity of particles on that surface than the standard depth filters.

Filter Options

Depth filtration products such as Critical Process Filtration Melt-Blown Polypropylene or Nano-Spun Polypropylene cartridges are commonly used for particulate removal. These products will hold a large quantity of particulates before requiring replacement. Yarn wound filters are another depth filter technology, but seldom utilized in pharmaceutical application due to extractables and particle shedding. Additionally, the superior construction of Critical Process Filtration's Melt-Blown or Nano-Spun filters ensures consistent particle removal unmatched by yarn wound filters.

Depending on the type of particles in the fluid streams, an economical alternative to standard depth filters may pleated media filters. Pleated filtration products, such as pleated polypropylene depth filters, have several times more surface area than melt-blown or nano-spun depth filters and will hold a much higher quantity of particles. Pleated filters do generally cost more, but the increased life in high-particle-load applications and capital savings from reduced number of cartridges required for batch processes may make pleated filters economically advantageous.

Contact Critical Process Filtration for assistance in determining the best filter options for your system

Filter Media Options for Particle Filtration in Small Molecule Drug Production

Process Area	Filter Application	Filtration Function	Media **
Prefiltration	Particle Reduction	Reduce particulate load to protect performance of downstream water treatment processes	MB, NMMB, PD, GD

**Media Codes

MB = Melt-Blown Polypropylene Depth Media
NMMB = Melt-Blown Nylon Depth Media
NS = Nano-Spun Polypropylene Depth Media
PD = Pleated Polypropylene Depth Media
GD = Pleated Fiberglass Depth Media

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