

What is aseptic filling and what are its commercial advantages?

Everyone is talking about aseptic filling and its commercial benefits, but this raises two vital questions for any prospective adaptor:

1. What are the advantages offered by aseptic processing?
2. How exactly does it work?

In this white paper we are addressing these vital questions in a simple and straightforward manner so you can better understand how aseptic processing may benefit your products and how it can improve your profitability.

What exactly is aseptic processing?

Aseptic processing is quite simply a means of production, which excludes microbial contamination from the product. We will describe below the technical features that make it possible to provide a sterile environment for filling/sealing and to create a sterile product as well as sterile containers.

The Aseptic Chamber

An absolutely essential pre-requisite for sterile product manufacturing is the creation and maintenance of a sterile (aseptic) environment. There are two critical design objectives that must be achieved to make a sterile environment a reality:

1. An aseptic chamber must be designed that completely blocks any microorganisms present in the surrounding environment from entering the areas where aseptic filling and sealing is conducted.
2. The internal surfaces and equipment within this aseptic chamber must be fully sterilized.

The aseptic chamber is designed to have all air entering the chamber pass through bacterial retentive filters, and to operate at a positive air pressure relative to the external environment. This means all microbes that could enter the chamber are removed by HEPA or better quality air filters and prevented from entry by air sealing. Also, the entire interior of the chamber is sterilized by Hydrogen peroxide to a very high level of sterility assurance.

Sterilization of Product Containers and Caps

A bottle sterilizer operating inside the aseptic chamber uses a Hydrogen peroxide and hot air mist system to sterilize the entire bottle, both inside and out. In this sealed chamber, the bottle, or container, being used is sent through an infeed conveyor and picked up by bottleneck grippers mounted on the bottle sterilizer rotary turret. Hydrogen peroxide (H_2O_2) atomization nozzles are mounted in a hot air duct above a rotary joint in the turret to produce a hot air/ H_2O_2 mist that is fed into a manifold and distributed to nozzles mounted above each bottle gripper. The nozzle enters the bottle mouth but does not touch the interior of the bottle. The H_2O_2 mist is blown into the bottle, wetting the entire surface. Simultaneously, the exterior of the bottle is sprayed from either side with an atomized mist of H_2O_2 from a series of fixed spray heads. Hot air is then utilized, again without contacting the bottle surface, which enhances the sterilizing effect of the H_2O_2 .

The bottles are then transferred back to the neck gripper system and moved to the sterile water rinse section. Once they have been transferred, they are inverted by an external cam system where the inside of the bottles is rinsed using jet spray nozzle mounted on the rinse wheel below each bottle. This step efficiently removes any H_2O_2 residue leaving only a clean, sterile bottle. Simultaneously the exterior of the bottles is also rinsed with sterile water. Following the rinse the clean/sterile bottles are then returned to the upright position by means of an external cam at the discharge point. The neck grippers are also cleaned by rinsing with hot, sterile water prior to gripping the next bottle as it is removed from the infeed wheel.

Oriented, screw caps are supplied to the infeed of the cap sterilizer from the cap sorter in single file. The cap sterilizer consists of three sections; the first is where the caps are cleaned by a hot air spray to remove any foreign material, in the second section they are sprayed with H_2O_2 and in a third section the caps are treated with hot sterile air to enhance the anti-microbial effectiveness of the H_2O_2 . The caps are then dried before they are discharged to the feed chute and which delivers them to the cap feed and placement mechanisms.

How does aseptic manufacturing increase product shelf life?

Microorganisms cause product degradation and ultimately will spoil product rendering it unusable. In conventional filling, the product (for example, milk) is filled in an open room with only minimal contamination control capability, rather than a sterilized environment as is the case in aseptic manufacturing. Since microorganisms are present in a conventional filling environment the product is at far greater risk of contamination and hence spoilage. When a fully sterile product is filled into sterilized containers and sealed with sterile caps inside an aseptic chamber, the risk of microbial contamination has been eliminated. The container and cap form an effective seal against the entry of microorganisms and therefore the product is sure to be sterile until it is opened by the consumer. Therefore, until the product is open there is no chance of spoilage arising from microbial contamination.

Does aseptic filling eliminate the need for refrigeration?

Although aseptically manufacturing products are sterile until opened and therefore free of any risk from microbial contamination, foods and beverages contain naturally occurring substances such as sugars and proteins that are susceptible to degradation. Cold storage and distribution can mitigate the risk of chemical or biochemical degradation of natural occurring ingredients.

What is the difference between aseptic filling systems and electron beam filling systems?

The Electron Beam Filling System is really just a subset of aseptic filling systems. Electron Beam is an alternate sterilization technology used to sterilize the container without chemicals (such as H_2O_2). Since the use of a chemical sterilant is avoided, the need for a post-sterilization rinse with sterile water is also eliminated. Electron Beam sterilization can reduce consumable materials costs and also greatly reduce water consumption. Functionally Electron Beam uses a focused "beam" of high-energy electrons to eliminate microorganisms on all surfaces, both interior and exterior, of PET bottles. H_2O_2 is still used, however, for the sterilization of caps and of the aseptic chamber.

What industries use aseptic filling?

Aseptic filling is used to safely manufacture a wide variety of food and beverage products, including milk, juices, and various tea/coffee drinks. Aseptic manufacturing is also widely used in healthcare for products that cannot withstand heat or radiation sterilization, this includes vaccines, biotechnology products, and many pharmaceuticals. The low acid beverages present the highest risk of microbial growth high acid beverages, because of their rather low pH, are naturally inhibitory to many microorganisms.

Why choose Shibuya for your aseptic needs?

Shibuya is a pioneer in aseptic chamber filling and has many years of experience in both chemical and Electron Beam Sterilization. Shibuya's expertise includes the development and validation of sterilization technologies used for both healthcare and food and beverage aseptic processing. Among the many technical benefits of a Shibuya Aseptic Filling System include:

- Up to 156 continuous product hours between cleaning and sterilization cycles
- The sterilization process is capable of very high levels of sterility assurance meeting or exceeding all international standards and regulatory requirements.
- Only six hours required for changeover including chamber sterilization. to re-sterilize the aseptic chamber
- There have been over 15 billion bottles produced on Shibuya Aseptic Filling Systems without any reports of microbial contamination or spoilage.
- Shibuya filling systems are the industry standard for product delivery accuracy resulting from our precision fill pumps and control systems.
- Shibuya has multiple successful FDA approvals to its credit.
- Our efficient and reliable Electron Beam technology provides our customers with an option to eliminate chemical bottle sterilization while at the same time reducing water consumption and improving environmental sustainability.
- Container neck handling provides processing stability, higher yields and extremely rapid changeover.
- The relatively small equipment footprint provides the customer with outstanding flexibility regarding equipment location.
- Our servo capper system provides 100% feedback and outstanding quality control on each cap application.
- Fully automated CIP/SIP of the product pathway as well as automatic chamber cleaning and sterilization
- Shortest lead times in the industry, equipment ready for installation in approximately 9-10 months after an order is placed.
- Short installation, commissioning and validation periods
- Shibuya can provide custom turnkey systems and provide after sales service originating from our various locations in the US