

Gamma Irradiated Bottle Assembly Systems

Single-use technologies are playing a key role in the reduction in risk of cross contamination in addition to time and cost benefits associated with assembly, cleaning and cleaning validation¹. Bio-Simplex™ Gamma Irradiated Bottle Assembly Systems are available in a range of commonly used sizes from 60mL to 2 Liter.

Each Bottle Assembly includes a 2 port EZ Top® Closure, made from C-Flex® pharmaceutical grade thermoplastic elastomer (TPE) resin and tubing, engineered to ensure an unobstructed fluid path, extremely low levels of extractables and a secure elastomeric seal between bottle and cap surfaces. Each Bottle System is equipped with a PETG bottle (2 Liter is poly-carbonate), a 0.2 µm vent filter, an 18" length of 1/8" ID x 1/4" OD C-Flex tubing with a plug end, notched dip tube to the bottom of the bottle and a polyethylene cap (polypropylene on 2 Liter). Economically designed for the single-use market, sample bottle assemblies are easily used with sterile connecting devices and thermal tubing sealers.

Bio-Simplex™ Gamma Irradiated Bottle Assembly Systems are sold as single items, each double bagged and gamma irradiated for a Sterility Assurance Level (SAL) of 10⁻⁶.

Customer-generated designs, sizes, packaging and other options — such as connectors, heat-sealed ends or alternate materials — are available as custom orders.

¹As noted in *Pharmaceutical Technology Europe*, January, 2006.



Bio-Simplex™ Gamma Irradiated Bottle Assembly Systems, in sizes from 60mL to 2 Liters, feature the EZ Top® Closure, filter, C-Flex® tubing, bottle and cap.



Closeup of a 125mL gamma irradiated bottle showing the EZ Top® Closure.

BIO-SIMPLEX™ GAMMA IRRADIATED BOTTLE ASSEMBLY SYSTEMS

60mL	SA24MM-60-2F
125mL	SA38MM-125-2F-DB
250mL	SA38MM-250-2F-DB
500mL	SA38MM-500-2F-DB
1000 mL (1L)	SA38MM-1L-2F-DB
2000 mL (2L)	SA38MM-2LPC-2F

For more detailed specs on Bio-Simplex™ Gamma Irradiated Bottle Assemblies, please see our product spec sheets.

BIOPHARMACEUTICAL PRODUCTS

Come through clean.™

Gamma Irradiated Bottle Assembly Systems

The diagram illustrates a Gamma Irradiated Bottle Assembly System. It features a clear plastic bottle with a grey stopper. A clear plastic tube is connected to the stopper and extends into the bottle. A vent filter is attached to the top of the stopper. A separate piece of clear plastic tubing is shown to the left of the bottle.

- Gamma Irradiated Bottle Assembly Systems include 18" of C-Flex[®] pharmaceutical grade thermoplastic elastomer (TPE) tubing with a plugged end.
- 1/8" ID x 1/4" OD C-Flex[®] tubing material is compatible with sterile connecting devices and tube welders.
- Standard polyethylene cap for 60mL-1L sizes; polypropylene cap for 2L size.
- PETG bottles in 60mL-1L sizes; Polycarbonate in 2L size.
- 0.2 μm 25mm vent filter allows sterile gas exchange.
- Thermal bond between stopper and tubing prevents compromise of product.
- EZ Top[®] closure of high purity C-Flex[®] pharmaceutical grade TPE provides integral seal to glass, plastic and metal. (See FLS-7201-0408-SGPPL-TPA)
- Provided gamma irradiated and double bagged.
- Bio-Simplex[™] Gamma Irradiated Bottle Assembly Systems are available in standard 60, 125, 250 or 500 mL and 1 or 2 Liter sizes.
- Customer-generated designs, sizes, packaging and other options — such as connectors, heat-sealed ends or alternate materials — are available as custom orders.

Ez Top[®] and C-Flex[®] are registered trademarks.
Bio-Simplex[™] and FlexJoint[™] are trademarks.

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