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 validation\(^1\). 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.

\(^1\)As noted in *Pharmaceutical Technology Europe*, January, 2006.

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**BIO-SIMPLEX™ GAMMA IRRADIATED BOTTLE ASSEMBLY SYSTEMS**

<table>
<thead>
<tr>
<th>Size</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>60mL</td>
<td>SA24MM-60-2F</td>
</tr>
<tr>
<td>125mL</td>
<td>SA38MM-125-2F-DB</td>
</tr>
<tr>
<td>250mL</td>
<td>SA38MM-250-2F-DB</td>
</tr>
<tr>
<td>500mL</td>
<td>SA38MM-500-2F-DB</td>
</tr>
<tr>
<td>1000mL (1L)</td>
<td>SA38MM-1L-2F-DB</td>
</tr>
<tr>
<td>2000mL (2L)</td>
<td>SA38MM-2LPC-2F</td>
</tr>
</tbody>
</table>

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

- Gamma Irradiated Bottle Assembly Systems include 18” of C-Flex® pharmaceutical grade thermoplastic elastomer (TPE) tubing with a plugged end.

- 0.2 µm 25mm vent filter allows sterile gas exchange.

- Standard polyethylene cap for 60mL-1L sizes; polypropylene cap for 2L size.

- Thermal bond between stopper and tubing prevents compromise of product.

- PETG bottles in 60mL-1L sizes; Polycarbonate in 2L size.

- EZ Top® closure of high purity C-Flex® pharmaceutical grade TPE provides integral seal to glass, plastic and metal. (See FLS-7201-0408-SGPLL-TPA)

- Provided gamma irradiated and double bagged.

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

- Bio-Simplex™ Gamma Irradiated Bottle Assembly Systems are available in standard 60, 125, 250 or 500 mL and 1 or 2 Liter sizes.

- 1/8”ID x 1/4”OD C-Flex® tubing material is compatible with sterile connecting devices and tube welders.

- 0.2 µm 25mm vent filter allows sterile gas exchange.

- 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.