

DE 70% in WFI 4 x 5L (0.2 μ Filtered – Bio-Burden Reduced)

Packaging:

- All components are prepared in a controlled environment prior to Irradiating (Grade C - ISO Class 7).
- All components are gamma irradiated 25kGy – 45 kGy prior to filling.

Manufacturing Bulk Fluid:

- All bulk fluid is manufactured in a controlled environment.
- All bulk fluids are filtered to 0.2 μ at point of fill.
- All bulk fluids are manufactured using High Purity Water (WFI Quality) guaranteeing a low endotoxin level.

Filling Conditions:

- All containers are filled under Laminar Air Flow (Grade A) within a Grade C Clean Room.
- The product is filtered to 0.2 μ at point of fill.
- Finished product is double bagged in a Grade C Clean Room.

