

Tryptic Soy Broth Products

Irradiated for Media Fill Applications

Production of Sterile Drugs by Aseptic Processing

Aseptic manufacturing is one of the most demanding operations conducted in the pharmaceutical industry. The major concern regarding product quality centers about sterility assurance for the drug product and the ability to consistently produce a sterile product. Aseptic processing is a systemized process involving several individual contamination control elements. Sterile filtration is the key element utilized for the removal of viable contaminants in the process. A validated sterility assurance program must be in place to insure final product quality specifications.

Aseptic Process Simulation – The Media Fill Test

One critical requirement for sterility assurance to test overall process sterility by performing a simulated production (media fill) using microbiological growth medium, in place of actual product. Media fills are a “worst case” challenge to a process, as pharmaceutical products typically do not support microbiological growth. This has caused concern from some drug manufacturers as microbiological culture media can themselves be a potential source of viable contamination. The production of dehydrated culture media is not a sterile process and biological components can contribute viable contamination. An effective approach to preventing media related contamination, (positive media fill tests) and eliminating the handling involved with traditional media preparation, is terminal sterilization of the dehydrated culture media by irradiation.

Merck KGaA Irradiated Tryptic Soy Broth Products

Merck KGaA is your first choice for innovative quality products for your sterility assurance program. Our irradiated animal and non-animal derived Tryptic Soy Broth products will insure the integrity of your aseptic process simulations. These granulated formulations are rigorously validated for sterility, growth performance and filtration characteristics. These products comply with the compendia and guidance documents for media fill applications world wide.





*5 kg Container
Triple Wrapped*

The key advantages of Merck KGaA irradiated media include:

Features:	Benefits:
Triple wrapped ready for Cleanroom use	Add directly to production vessels in manufacturing area. No advance preparation required
Irradiation process using 48–68 kGy gamma	Validated process insures against media related positive aseptic process simulations caused by bacteria, yeast, mold, bacterial spores or mycoplasma.
Each Lot is Mycoplasma Tested	Validated QC testing process for mycoplasma to insure against the presence of this difficult contaminant.
Growth promoted at sterility tested at 20–25°C and 30–35°C.	Guarantees highest level of performance
Certificates of Origin and Suitability	Complete traceability documentation to ensure compliance with BSE/TSE requirements.
Excellent filterability/solubility	Prolongs filter life during media fills as compared to traditional powdered media, saving money by reducing filter changes.
Exclusive Granulated Format	Reduced dust during preparation, easier to handle while improving solubility.

Product Ordering Information:

Part Number	Description	Pack Size
1.00800.5000	Tryptic Soy Broth, Irradiated	5 kg
1.00550.5000	Tryptic Soy Broth, Non Animal, Irradiated	5 kg

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