



**HiVeg**

Animal Free Culture Media & Ingredients

## Why contaminate your sterile line with Animal Products??

When it can be swift and safe with HiFill™ HiVeg™ Media

# MFT

## Media Fill Trial

Media fill studies, simulates the filling process during production and helps in detecting contamination in the production line, if any. Generally the commercial media is prepared, autoclaved and after filtering through a 0.2 micron sterilizing filter is used to investigate presence or absence of contamination. To make the process faster, efficient and safer; HiMedia provides **gamma irradiated dehydrated culture media** which can be directly used. Soyabean HiVeg™ medium sterile powder, γ-irradiated from vegetable source can be used.

### 3 - General Considerations

#### 3-1: Scientific Principles for Minimising risk

*"When manufacturers have a choice, the use of materials from 'non TSE-relevant animal species' or non-animal origin is preferred"*

Source EP 8.0,2014 <Section 5.2.8>

Minimising the risk of transmitting TSE via medicinal products

## Animal Free Media **MV011G**

Soyabean HiVeg™ Medium, Sterile Powder

## Gamma Irradiated Medium for Media Fill Trial

Also available classical Tryptone Soya Broth as per USP **MH011G / GMH011G** \*

\* Granulated form

Switch now to

# Media Fill : Maximum Benefits & Minimizing Risks with HiVeg™ Gamma Irradiated TSB.



Media fills simulate the whole process in order to evaluate the sterility confidence of the process. Process simulation studies include formulation, filtration and filling with suitable media. In general, a microbiological growth medium such as Tryptic Soy Broth should be used. Use of anaerobic growth media (e.g. Fluid Thioglycollate medium) should be considered in special circumstances.

With the spurt in number of BSE symptoms across global bovine population & and its exhibit CJD in humans concerns were raised about bovine origin products.

Elimination of BSE/TSE Risk can be achieved by use of raw material from right origin & right parts of the animal. Definition of Risk Categories by EU:

- Category A: High infectivity (e.g. brain, spinal cord)
- Category B: Moderate infectivity (e.g. spleen, lung, liver)
- Category C: No infectivity found (e.g. milk, bile, skeletal muscle, heart, skin)

HiMedia only sources from risk category 'C' for its products. Moreover as per the Definition of Geographical BSE Risk by EU, raw material sourced from India has no listings. In spite of such a proven track record of quality, a step further to provide more secure process HiVeg™ culture media was launched. Both USP & EP preferred or recommend that alternative, non-animal source ingredients be substituted for animal-source ingredients whenever possible.

The risk of Mycoplasma is always lurking in the raw material. Moreover Mycoplasma can move through 0.2 micron filters & Reach high titers ( $10^7$  –  $10^8$  cfu/ml) without producing pH changes or media turbidity proving itself as invisible threat. In such cases a prudent step ahead to provide maximum quality assurance is to provide  $\gamma$ -irradiated TSB.

$\gamma$ - Irradiation does not affect product performance, and results in a Contaminant-free material, this has been evaluated by comparative studies on growth performance of pharmacopoeia listed pathogens. Thus HiVeg™  $\gamma$ -irradiated TSB is the choice of a prudent quality system.

Introduced gamma irradiated HiFill™ Test Medium recommended for the evaluation of sterility in manufacturing process for easy detection of contamination. The medium is designed with TSB containing an MFT indicator wherein the colour change is from yellow to pink red.

## Reference:

- The USP Perspective to Minimize the Potential Risk of TSE-infectivity in Bovine-derived Articles Used in the Manufacture of Medical Products; with Ian DeVeau and Roger Dabbah. Pharmacopoeial Forum. 30(5):1911-1921. 2004
- European Pharmacopoeia (Supplement 6.3), 2008, European Department, for the Quality of Medicines

HiMedia No.	Product Range for Media Fill trials
M011G-500G M011G-2.5KG M011G-5KG	Tryptone Soya Broth, Sterile Powder $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.
MV011G-500G MV011G-2.5KG MV011G-5KG	Tryptone Soya <b>HiVeg</b> Broth, Sterile Powder $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.
GMV011G-500G	Tryptone Soya <b>HiVeg</b> Broth, Granulated, Sterile $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.
MH011G-500G	Tryptone Soya Broth, Sterile powder $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.
GMH011G-500G	Tryptone Soya Broth, Granulated, Sterile powder $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.
M1856G-500G M1856G-2.5KG	Tryptone Soya Broth w/ Mannitol, Sterile Powder $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process. It can also be used for cultivation of a wide variety of microorganisms.
M1655G-500G M1655G-2.5KG M1655G-5KG	Tryptone Soya Broth w/ BCP, Sterile Powder $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process. It can be also used for the fermentation studies.
M010G-500G M010G-2.5KG M010G-5KG	Alternative Thioglycollate Medium, Sterile Powder $\gamma$ -irradiated sterile powder recommended for evaluation of sterility in manufacturing process.
MV010G-500G MV010G-2.5KG MV010G-5KG	Alternative Thioglycollate <b>HiVeg</b> Medium, Sterile Powder $\gamma$ -irradiated sterile powder recommended for evaluation of sterility in manufacturing process.
MU010G-500G MU010G-2.5KG MU010G-5KG	Alternative Thioglycollate Medium, Sterile Powder $\gamma$ -irradiated sterile powder recommended for evaluation of sterility in manufacturing process in accordance with USP.
M2018G-500G	HiFill™ Test Medium $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process for easy detection of contamination by Media Fill Test.
MV2018G-500G	HiFill™ Test <b>HiVeg</b> Medium $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process for easy detection of contamination by Media Fill Test.
MCD2018G-500G	HiFill™ Test HiCynth™ Medium $\gamma$ -irradiated sterile powder recommended for the evaluation of sterility in manufacturing process for easy detection of contamination by Media Fill Test.
RM565G-5KG RM565G-50KG	Lactose monohydrate, Sterile ( $\gamma$ irradiated sterile powder)
RM565GT-5KG	Lactose monohydrate, Sterile Powder ( $\gamma$ irradiated Triple Pack)
RM570G-5KG RM570G-50KG	D-Mannitol, A. R. sterile ( $\gamma$ irradiated)

Bulk packing are available on request for all above products.

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