

## Soyabean HiVeg™ Medium (Tryptone Soya HiVeg™ Broth) Granulated, Sterile

GMV011G

Soyabean HiVeg™ Medium, granulated, sterile is a gamma-irradiated medium recommended for the evaluation of sterility in manufacturing process

### Composition\*\*

<b>Ingredients</b>	<b>Gms / Litre</b>
HiVeg hydrolysate	17.000
Papaic digest of Soyabean meal	3.000
Sodium chloride	5.000
Dipotassium phosphate	2.500
Dextrose	2.500
Final pH ( at 25°C)	7.3±0.2

\*\*Formula adjusted, standardized to suit performance parameters

### Directions

Sterile medium can be used directly for the evaluation of sterility in manufacturing process. For sterile liquid medium aseptically add 30 grams in 1000 ml sterile distilled water. Heat if necessary to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Dispense aseptically in sterile tubes or flasks as desired.

### Principle And Interpretation

This medium is prepared by completely replacing animal based peptones with vegetable peptones. Soyabean HiVeg Medium is modification of Soyabean Casein Digest Medium is recommended by various pharmacopoeia as sterility testing medium (1, 2). It is also used for the sensitivity testing by the tube dilution method for antimicrobial agents (3).

The combination of HiVeg hydrolysate and papaic digest of soyabean meal makes this medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Dextrose and dipotassium phosphate serves as the carbohydrate source and the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

### Quality Control

#### Appearance

Cream to yellow coloured granular medium may have green tinge

#### Colour and Clarity of prepared medium

Light amber coloured clear solution

#### Reaction

Reaction of 3.0% w/v aqueous solution at 25°C. pH : 7.3±0.2

#### pH

7.10-7.50

#### Sterility Testing

No growth is observed after 14 days for Bacteria at 30-35°C and for Fungi at 20-25°C.

#### Test for Mycoplasma (PCR)

Negative for Mycoplasma

#### Stability test

Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days

#### Growth promoting properties

Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating ≤100cfu (at 30-35°C for 18-24 hours).

#### Sterility Testing + Validation

The medium is tested with suitable strains of microorganisms inoculating ≤100cfu and incubating at 20-25°C for not more than 3 days in case of bacteria and not more than 5 days in case of fungi.

**Cultural Response**

<b>Organism</b>	<b>Inoculum (CFU)</b>	<b>Growth</b>	<b>Incubation temperature</b>	<b>Incubation period</b>
<b>Growth promoting</b>				
<i>Staphylococcus aureus</i> ATCC 6538	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus</i> ATCC 25923	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 8739	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 25922	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> NCTC 9002	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Bacillus subtilis</i> ATCC 6633	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Micrococcus luteus</i> ATCC 9341	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Typhimurium ATCC 14028	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Abony NCTC 6017	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Streptococcus pneumoniae</i> ATCC 6305	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<b>Sterility Testing- Growth promotion+ Validation</b>				
<i>Staphylococcus aureus</i> ATCC 6538	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Staphylococcus aureus</i> ATCC 25923	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> ATCC 8739	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> ATCC 25922	50 -100	luxuriant	20 -25 °C	<=3 d
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<i>Salmonella</i> Typhimurium ATCC 14028	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Salmonella</i> Abony NCTC 6017	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Streptococcus pneumoniae</i> ATCC 6305	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Candida albicans</i> ATCC 10231	50 -100	luxuriant	20 -25 °C	<=5 d
<i>Candida albicans</i> ATCC 2091	50 -100	luxuriant	20 -25 °C	<=5 d
* <i>Aspergillus brasiliensis</i> ATCC 16404	50 -100	luxuriant	20 -25 °C	<=5 d

**Storage and Shelf Life**

Store below 10-30°C in tightly closed container and prepared medium at 2-8°C. Use before expiry period on the label.

**Reference**

Please refer disclaimer Overleaf.

1. The United States Pharmacopoeia, 2014, The United States Pharmacopoeial Convention, Rockville, MD.
2. Indian Pharmacopoeia, 2014 Ministry of Health and Family Welfare, Govt. of India.
3. Wright and Welch, 1959-60, Antibiotics Ann., 61.

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