

**Tryptic soy broth non animal origin irradiated, triple wrapped****84855.0500****84855.5000****Also known as**

Soyabean HiVeg Medium, Sterile Powder

**Intended use**

A gamma-irradiated sterile medium recommended for the evaluation of sterility in manufacturing process.

**Formula\*\*- Composition in g/L**

<b>Ingredients</b>	<b>g/L</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

**Instructions for preparation**

Tryptic Soy Broth Non Animal Origin Irradiated can be used directly for the evaluation of sterility in manufacturing process. For sterile liquid medium aseptically add 30 grams in 1000 ml sterile purified/ distilled water. If required boil to dissolve the medium completely. Dispense aseptically in sterile tubes or flasks as desired.

**Principle of the method and general information**

This medium is prepared by completely replacing animal based peptones with vegetable peptones. Tryptic Soy Broth Non Animal Origin Irradiated 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.

**Instructions for use**

1. Medium is prepared as directed above.
2. Sterile prepared medium can be used for the simulation of the aseptic filling of liquids.

**Limitations**

Some strains may fail to grow or may show poor growth on this medium

**Quality Control****Appearance**

Cream to yellow homogeneous free flowing powder

**Colour and Clarity of prepared medium**

Light amber coloured clear solution

**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. No growth of Mycoplasma after 14 days at 35-38°C under microaerophilic condition

### Growth Promotion Test

Growth promotion is carried out by incubation at 30-35°C for 18-24 hours.

### Stability test

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

### Sterility Testing + Validation

The medium is tested with suitable strains of microorganisms inoculating  $\leq 100$ cfu 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

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation period
<b>Growth promoting</b>				
<i>Staphylococcus aureus</i> ATCC 25923	50 -100	good	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus</i> ATCC 6538	50 -100	good	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 8739	50 -100	good	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 25922	50 -100	good	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> NCTC 9002	50 -100	good	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	good	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	good	30 -35 °C	18 -24 hrs
<i>Bacillus subtilis</i> ATCC 6633	50 -100	good	30 -35 °C	18 -24 hrs
<i>Micrococcus luteus</i> ATCC 9341	50 -100	good	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Typhimurium ATCC 14028	50 -100	good	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Abony NCTC 6017	50 -100	good	30 -35 °C	18 -24 hrs
<i>Streptococcus pneumoniae</i> ATCC 6305	50 -100	good	30 -35 °C	18 -24 hrs

### Sterility Testing- Growth promotion+Validation

<i>Staphylococcus aureus</i> ATCC 6538	50 -100	good	20 -25 °C	$\leq 3$ d
<i>Staphylococcus aureus</i> ATCC 25923	50 -100	good	20 -25 °C	$\leq 3$ d
<i>Escherichia coli</i> ATCC 8739	50 -100	good	20 -25 °C	$\leq 3$ d
<i>Escherichia coli</i> ATCC 25922	50 -100	good	20 -25 °C	$\leq 3$ d
<i>Escherichia coli</i> NCTC 9002	50 -100	good	20 -25 °C	$\leq 3$ d
<i>Pseudomonas aeruginosa</i> ATCC 9027	50 -100	good	20 -25 °C	$\leq 3$ d

<i>Pseudomonas aeruginosa</i> ATCC 27853	50 -100	good	20 -25 °C	<=3 d
<i>Bacillus subtilis</i> ATCC 6633	50 -100	good	20 -25 °C	<=3 d
<i>Micrococcus luteus</i> ATCC 9341	50 -100	good	20 -25 °C	<=3 d
<i>Salmonella</i> Abony NCTC 6017	50 -100	good	20 -25 °C	<=3 d
<i>Streptococcus pneumoniae</i> ATCC 6305	50 -100	good	20 -25 °C	<=3 d
<i>Candida albicans</i> ATCC 10231	50 -100	good	20 -25 °C	<=5 d
<i>Candida albicans</i> ATCC 2091	50 -100	good	20 -25 °C	<=5 d
<i>Aspergillus brasiliensis</i> ATCC 16404	50 -100	good	20 -25 °C	<=5 d

#### Reference

1. The United States Pharmacopoeia / National Formulary, 2002, 25/20, The United States Pharmacopoeial Convention Inc., Rockville, MD.
2. Indian Pharmacopoeia, 1996, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
3. Wright and Welch, 1959-60, Antibiotics Ann., 61.

#### Storage conditions

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

#### Ordering Information

84855.0500	Tryptic soy broth non animal origin irradiated, triple wrapped	Bottle of 500g
84855.5000	Tryptic soy broth non animal origin irradiated, triple wrapped	Bottle of 5 kg