BH1261	**SOYABEAN CASEIN DIGEST MEDIUM (TRYPTONE SOYA BROTH)**
Formula	
Ingredients:	**gms/lit.**
Tryptone	17.00
Soya peptone	3.00
Sodium chloride	5.00
Dipotassium hydrogen phosphate	2.50
Glucose monohydrate	2.50
Final pH (at 25°C): 7.3 + 0.2	

Directions:

Suspend 29.77 grams (the equivalent weight of dehydrated medium per liter) in 1000 ml purified/ distilled water. Heat, if necessary, to dissolve the medium completely. Dispense in tubes or flasks as desired. Sterilize by autoclaving at 15lbs pressure (121°C) for 15 minutes or as per validated cycle.
Note: If any fibres are observed in the solution, it is recommended to filter solution through a 0.22-micron filter to eliminate the possibility of presence of fibres.

Principle:

The combination of tryptone and soya peptone makes this medium nutritious by providing nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other minerals for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose monohydrate is the fermentable source of carbon and dipotassium hydrogen phosphate serves as the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

QC Tests – (I)Dehydrated Medium		
	Colour:	Cream to yellow
	Appearance:	Homogeneous Free Flowing powder
(II)Rehydrated medium		
	pH (post autoclaving/heating):	7.3 ± 0.2
	Colour (post autoclaving/heating):	Light yellow
	Clarity (post autoclaving/heating):	Clear
	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 <=100 cfu(at 30-35°C for 18-24 hours for bacteria and 5 days for fungal). Growth promotion is carried out as per USP/EP/BP/JP.
	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.

(III)Growth promoting

	MICROORGANISM (ATCC)	**GROWTH**	**INCUBATION PERIOD**	**INOCULUM (CFU)**	**INCUBATION TEMPERATURE**
	Salmonella Abony (NCTC 6017)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Streptococcus pneumoniae (6305)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Escherichia coli (NCTC9002)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Escherichia coli (25922)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Escherichia coli (8739)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C

	Pseudomonas aeruginosa (27853)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Pseudomonas aeruginosa (9027)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Bacillus subtilis (6633)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Micrococcus luteus (9341)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Salmonella Typhimurium (14028)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Staphylococcus aureus (25923)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Staphylococcus aureus (6538)	Luxuriant	18 -24 hrs	50 -100	30 -35 °C
	Sterility Testing- Growth promotion+Validation				
	Candida albicans (10231)	Luxuriant	<=5 d	50 -100	30 -35 °C
	Candida albicans (2091)	Luxuriant	<=5 d	50 -100	30 -35 °C
	Salmonella Abony (NCTC 6017)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Aspergillus niger (16404)	Luxuriant	<=5 d	50 -100	30 -35 °C
	Streptococcus pneumoniae (6305)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Escherichia coli (NCTC9002)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Escherichia coli (25922)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Escherichia coli (8739)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Pseudomonas aeruginosa (27853)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Pseudomonas aeruginosa (9027)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Micrococcus luteus (9341)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Salmonella Typhimurium (14028)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Staphylococcus aureus (25923)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Staphylococcus aureus (6538)	Luxuriant	<=3 d	50 -100	20 -25 °C
	Bacillus subtilis (6633)	Luxuriant	<=3 d	50 -100	20 -25 °C

Precautions :	1. For Laboratory Use.
	2. Follow proper, established laboratory procedures in handling and disposing of infectious materials.
Limitations :	1. This medium is general purpose medium and may not support the growth of fastidious organisms.
	2. Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.
Use:	A general-purpose medium used for cultivation of a wide variety of microorganisms and sterility testing of molds and lower bacteria from pharmaceutical products in accordance to microbial limit testing by harmonized system of USP/BP/EP/JP.
Storage:	Dehydrated medium-Between 10-30°C Prepared medium– Between 15 to 25°C.
Packing:	500 gm. bottle

Product profile:	Reconstitution	Quantity on Preparation (500g)	pH (25°C)	Supplement	Sterilization
BH1261	29.77 g/l	16.79 L	7.3 ± 0.2	Nil	121^0C/ 15 min.