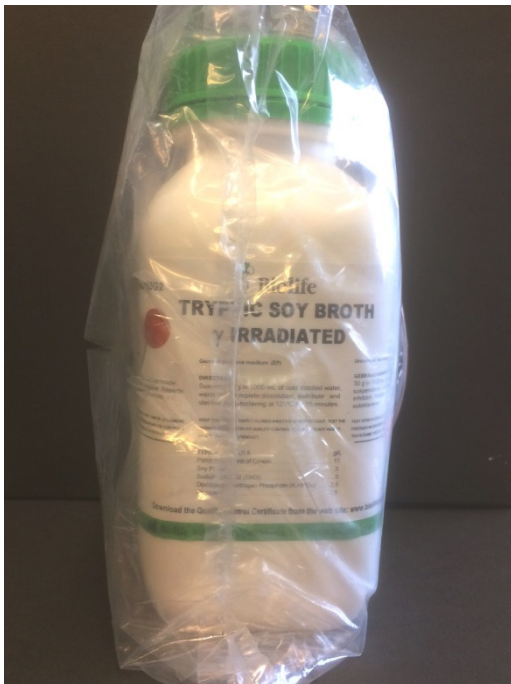




TRYPTIC SOY BROTH GAMMA IRRADIATED

Gamma irradiated dehydrated multipurpose medium
for the growth of a wide variety of microorganisms



INTENDED USE

Gamma irradiated multipurpose medium that supports the growth of a wide variety of microorganisms. This medium is suitable for sterility testing and for the validation of bottling plants with the Media Fill Test.

PACKAGING

The 500g bottles and the powder in the 5kg drums, are packed in a double plastic wrap.

IRRADIATION

The medium in 500g and 5kg packs with double wrapping is subjected to treatment with gamma rays at a minimum dose of 25 kGy and maximum of 35 kGy. Different doses can be applied based on specific agreements with the customer.

TYPICAL FORMULA (G/L)*

Pancreatic Digest of Casein	17.0
Soy Peptone	3.0
Sodium Chloride	5.0
Dipotassium Hydrogen Phosphate	2.5
Glucose	2.5

*The medium can be adjusted to adapt its performance to specifications

PREPARATION OF THE DEHYDRATED CULTURE MEDIUM

Dissolve 30 g in 1000 mL of sterile purified water, stirring the solution. Use for validation procedures.

CHEMICAL AND PHYSICAL CHARACTERISTIC

Powder appearance: fine, homogeneous, straw yellow

Melted medium appearance: straw yellow, clear

Final pH: 7,3 ± 0,2

PRINCIPLE OF THE METHOD

Tryptic Soy Broth γ Irradiated, prepared according to the formulation described by EP, is a general use medium that supports the growth of a wide variety of microorganisms. Quality control is carried out on the medium before and after irradiation and includes bioburden and powder sterility testing and productivity tests. The medium is indicated for the sterility test and for the validation of the bottling plants with the Media Fill Test.

Refer to the methods reported by the current European Pharmacopoeia for the procedures to be adopted. The presence of microorganisms is indicated by the cloudiness of the culture broth or by the presence of a sediment on the bottom of the recipients. The characteristic of the growth is closely related to the type of microorganism.



QUALITY CONTROL

It is responsibility of the user to perform quality control tests in accordance with the regulations and according to his own Laboratory experience. The following table shows some useful strains for quality control.

CONTROL STRAINS				INCUBATION T° / t / ATM	EXPECTED RESULTS
<i>B.subtilis</i>	ATCC	6633	10-100 UFC	20-25 °C / 24 h -A	Good growth
<i>C.albicans</i>	ATCC	10231	10-100 UFC	20-25 °C / 72-120h -A	Good growth
<i>A.brasiliensis</i>	ATCC	16404	10-100 UFC	20-25 °C / 72-120h -A	Good growth
<i>E.coli</i>	ATCC	8739	10-100 UFC	35-37 °C / 24 h -A	Good growth
<i>S.aureus</i>	ATCC	6538	10-100 UFC	35-37 °C / 24 h -A	Good growth
<i>P.aeruginosa</i>	ATCC	9027	10-100 UFC	35-37 °C / 24 h -A	Good growth

Note

Incubation atmosphere A: aerobic incubation

ATCC is a registered trade mark of American Type Culture Collection; NCTC is a registered trade mark of National Collection of Type Cultures.

STORAGE

Store at 10-30 °C, in a dark place. When stored as directed, the medium remains stable until the expiry date shown on the label. Do not use beyond stated expiry date.

Discard if there are any obvious signs of deterioration (color changes, hardening etc.).

PRECAUTIONS

The medium described here is not classified as dangerous according to current legislation.

As for all the dehydrated media, the handling of this product must be carried out with adequate protection of the respiratory tract.

REFERENCES

- European Pharmacopoeia, current edition.

PRODUCTS

Description	Type	Cat. N°	Package
TRYPTIC SOY BROTH GAMMA IRRADIATED	Dehydrated Culture Medium	402155G2	500 g (16,7 L)
		402155G4	5 kg (167 L)



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