

Reference: 07-197 Product: TRYPTOSE

Specification

Culture Media Ingredient.

Description

Tryptose is a mixed peptone with high nutrient properties that make it appropriate for the use in culture media for very fastidious microorganisms. Among the raw materials used in its preparation, the bovine constituents (milk casein) belong to the category C according to "*Note for Guidance* EMEA/410/01 Rev. 3". The milk casein is sourced from New-Zealand, and comes from herds declared free from Bovine Spongiform Encephalopathy and Foot-and-Mouth disease after examination by the Veterinary Authorities.

The product does not contain and is not derived from specified risk material as defined in the European Commission Decision 97/534/EC. Also it complies with the General Monograph 1483 on "Products with Risk of Transmitting Agents of Animal Spongiform Encephalopathies" in the current European Pharmacopoeia.

The other constituents are of porcine origin. The manufacturing process includes boiling at 100°C for a minimum of 5 minutes and instantaneous heating at 170°C minimum on spray drying.

(Note: These parameters can be changed and specified in the Certificate of Analysis for each batch).

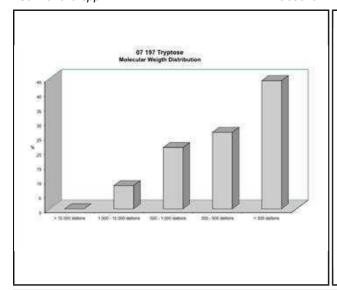
Finally, it's according with Reg. (EC) No 1069/2009 for the manufacturing of intermediate and pharmaceutical products.

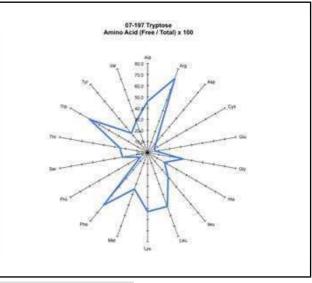
Physico-chemical characteristics

Appearance podwer	. Yellow to beige
Solubility in water 5%	. Total
Stability after autoclave	. No precipitate
Loss on drying (% Moisture)	. ≤ 6,00
pH (solution 2%)	6,8 -7,2
Amino Total TN (% w/w)	. 12,0 - 13,5
Amino Nitrogen AN (% w/w)	3,5 - 5,0
AN/TN x100	25-33
Chlorides (NaCl)(%)	. Max. 1,0
Residue on ignition (%)	. Max. 20,0

Microbiological limits

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Total aerobic microbial count	< 10000 CFU/g
Coliforms	< 10 CFU/g
Moulds and yeasts	< 20 CFU/g
Staphylococcus aureus	absent in 10 g
Escherichia coli	absent in 10 g
Salmonella spp	absent in 25 g





Revision date: 11/02/2020

Storage

For laboratory use only. Keep tightly closed, away from bright light, in a cool dry place (+4 °C to 30 °C).