

Specification

Culture Media Ingredient.

Description

The Peptone from Casein is a protein hydrolysate obtained from trypsin-digested casein according to the USP specifications. Both its nitrogen concentration and its balanced amino-acid composition provide an adequate support for microbial growth and is used in the production of culture media, resulting in exceptionally clear solutions. The digestion and production process uses an exceptionally trypsin-rich enzymatic preparation which produces a high content of tryptophane and ensures the absence of fermentable sugars and enzymatic activity. 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 used is sourced from New-Zealand, and come 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 96°C for a minimum of 25 minutes and instantaneous heating at 200°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) N° 1069/2009 for the manufacturing of intermediate and pharmaceutical products.

Physico-chemical characteristics

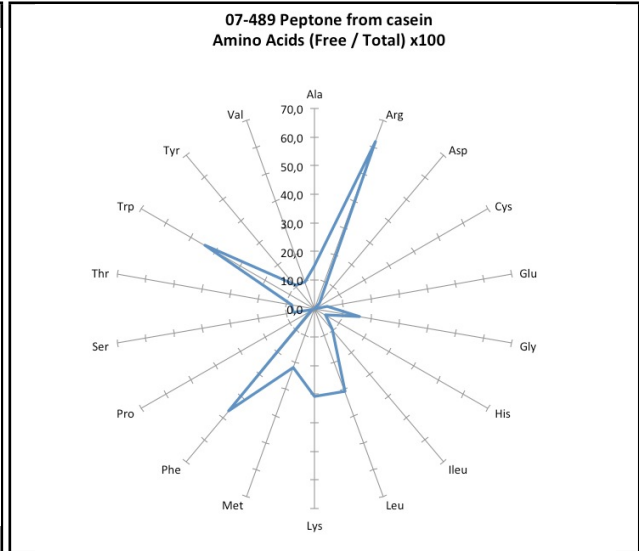
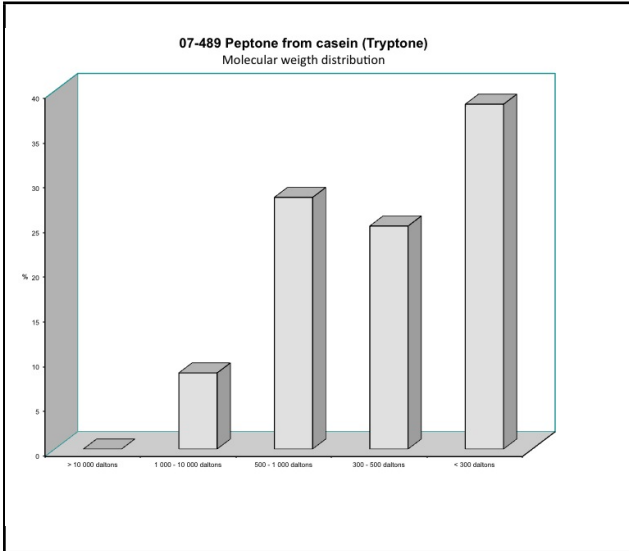
Appearance powder.....	Yellow to beige
Solubility in water 5 %	Total
Stability after autoclaving.....	No precipitate
Loss on drying (% Moisture).....	≤ 6.00
pH after autoclaving (solution 2%).....	6.8 -7.2
Total Nitrogen TN (% w/w).....	12.0 - 13.5
Amino Nitrogen AN (% w/w).....	3.0 - 4.5
AN/TN x100.....	25-33
Chlorides (NaCl)(%).....	≤ 1.00
Residue on ignition (%).....	≤ 15.00

Microbiological limits

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

Amino Acids (Total g/100 g)

Alanine.....	2.87	Isoleucine.....	4.48	Valine.....	5.51
Arginine.....	3.31	Proline.....	8.65	Lysine.....	6.51
Aspartic acid.....	6.52	Serine.....	5.08	Methionine.....	2.35
Cystine.....	0.40	Threonine.....	3.91	Histidine.....	2.29
Glutamic acid.....	18.70	Tryptophan.....	1.05	Leucine.....	7.63
Glycine.....	1.79	Tyrosine.....	1.86	Phenylalanine.....	4.09



Storage

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