Specification

Culture Media Ingredient.

Description

Casein Pancreatic Peptone is a protein hydrolysate, obtained by digestion with pancreatic enzyme extracts. It differs from Tryptone only in the way it is obtained, which produces a different amino acid composition with the majority being of a smaller molecular size. It is the most commonly used peptone in industrial fermentation processes. 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 the 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.Other constituents used are of porcine origin. The manufacturing process includes boiling at 100ºC for a minimum of 5 minutes and instantaneous heating at 170ºC 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

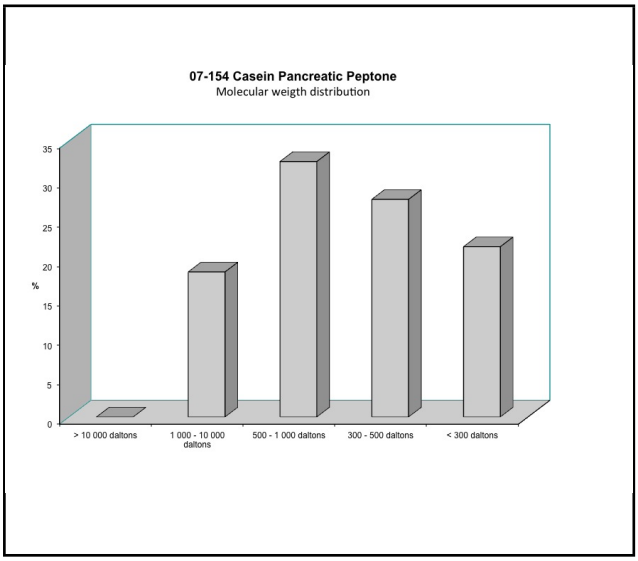
Appearance powder	Yellow to beige
Solubility in water 2 %	Total
Stability after autoclaving	No precipitate
Loss on drying (% Moisture)	≤ 6,00
pH after autoclaving (solution 2%)	6,5 -7,5
Total Nitrogen TN (% w/w)	> 10.00
Amino Nitrogen AN (% w/w)	> 3.9
AN/TN x100	N/A
Chlorides (NaCl)(%)	≤ 1.00
Residue on ignition (%)	≤ 17,00

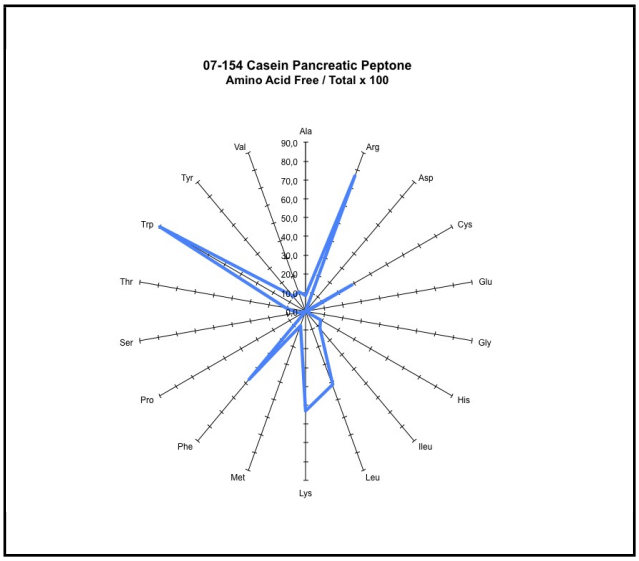
Microbiological limits

Total aerobic microbial count	< 10000 CFU/g
Coliforms	< 10 CFU/g
Moulds and yeasts	< 100 CFU/g
Staphylococcus aureus	absent in 10 g
Escherichia coli	absent in 10 g
Salmonella spp	absent in 25 g

Amino Acids (Total g/100 g)

Alanine	2.91	Isoleucine	4.45	Valine	5.51
Arginine	3.30	Proline	8.65	Lysine	6.60
Aspartic acid	6.99	Serine	5.08	Methionine	2.32
Cystine	0.44	Threonine	3.91	Histidine	2.38
Glutamic aicid	18.74	Tryptophan	0.95	Leucine	7.62
Glycine	1.86	Tyrosine	1.86	Phenylalanine	4.11





Storage

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