



SPECIFICATIONS

ULTRAMYL

Sodium starch glycolate Type A/ Sodium carboxymethyl starch Type A
conform to EP, NF, JP

Description

Almost white, fine, free-flowing powder, very hygroscopic, practically insoluble in methylene chloride. It gives a translucent suspension in water. Examined under a microscope it conforms to the description of Ph. Eur. Produced from potato starch without cross-linking agent.

Characteristics	Specification
Identification (NF A, B, C, D)	Passes
Identification (Ph. Eur. A, B, C, D)	Passes
Identification (JP 1, 2, 3)	Passes
Loss on drying	7.0% maximum
pH	5.5 - 7.5
Assay (Na ⁺ from starch glycolate)	2.8% - 4.2%
Sodium chloride	7.0% maximum
Residue of Methanol	3.0% maximum
Appearance of solution	Passes
Sodium glycolate	2.0% maximum
Heavy metals	20 ppm maximum
Iron	20 ppm maximum
<i>Microbial contamination</i>	
TAMC	<10 ² CFU/g
TYMC	<10 ² CFU/g
Staphylococcus aureus	Absent in 1 g
Pseudomonas aeruginosa	Absent in 1 g
Escherichia coli	Absent in 1 g
Salmonella	Absent in 10 g
Degree of Substitution	0.21 - 0.35
Setting volume	45 ml maximum

The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur.<5.4>, USP<467>) except for Methanol limited to < 3.0 %.

Storage: At ambient temperature, protected from humidity.

Packaging: 25 kg PE bag in paper box.

Shelf Life: 4 Years.