



Alifarma S.A. de C.V.

Sodium Starch Glycolate, Type A Ph. Eur., NF, JP Specifications

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 with a cross-linking agent.

Characteristics

Identification (NF A, B, C, D)
Identification (Ph. Eur. A, B, C, D)
Identification (JP 1, 2, 3)
pH
Loss on drying
Assay (Na⁺ from Starch glycolate)
Sodium chloride
Residue of Ethanol
Appearance of solution
Sodium glycolate
Heavy metals
Iron
Total aerobic microbial count (TAMC)
Total yeasts and molds count (TYMC)
E. coli, Pseudomonas aeruginosa
Staph. aureus, Salmonella spec.
Particle size [through 140 mesh (107 μm)]
Sulfated ash

Specification

passes
passes
passes
5.5 - 7.5
max. 10.0 %
2.8 - 4.2 %
max. 7.0 %
max. 3.0 %
passes
max. 2.0 %
max. 20 ppm
max. 20 ppm
< 1000 CFU/g
< 100 CFU/g
absent in 10 g
absent in 10 g
min. 99 %
max. 15.0 %

Reference

NF
Ph. Eur.
JP
Ph. Eur., NF, JP
Ph. Eur., NF, JP
Ph. Eur., NF, JP
Ph. Eur., NF, JP
JRS
Ph. Eur.
Ph. Eur., NF
JRS
JRS
Ph. Eur., USP
Ph. Eur., USP
Ph. Eur., USP
Ph. Eur., USP
JRS
JRS

The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur.<5.4>, USP<467>) nor any other solvents, except for Ethanol limited to < 3.0 %.

S Explotab 05.1

valid as of 2009-05-01

