

EXPLOTAB®

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

Specifications

Description

Appearance Almost white, fine, free-flowing powder, very hygroscopic
Solubility 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

Acceptance criteria

Reference

Identification (NF A, B, C, D)	Passes	NF
Identification (Ph. Eur. A, B, C, D)	Passes	Ph. Eur.
Identification (JP 1, 2, 3)	Passes	JP
Appearance of solution	Passes	Ph. Eur.
Assay (Na ⁺ from Starch glycolate)	2.8 - 4.2 %	Ph. Eur., NF, JP
Heavy metals	Max. 20 ppm	JRS Method
Iron	Max. 20 ppm	JRS Method
Loss on drying	Max. 10.0 %	Ph. Eur., NF, JP
pH	5.5 - 7.5	Ph. Eur., NF, JP
Sodium chloride	Max. 5.5 %	Ph. Eur., NF, JP
Sodium glycolate	Max. 2.0 %	Ph. Eur., NF, JP
TAMC (Total Aerobic Microbial Count)	10 ³ cfu/ g	Ph. Eur., USP, JP
TYMC (Total Yeasts and Molds Count)	10 ² cfu/ g	Ph. Eur., USP, JP
Escherichia coli	Absent in 1 g	Ph. Eur., USP, JP
Pseudomonas aeruginosa	Absent in 1 g	Ph. Eur., USP, JP
Salmonella species	Absent in 10 g	Ph. Eur., USP, JP
Staphylococcus aureus	Absent in 1 g	Ph. Eur., USP, JP
Particle size [through 140 mesh (106 µm)]	Min. 99 %	JRS Method
Sulfated ash	Max. 15.0 %	JRS Method
Residue of ethanol	Max. 3.0 %	JRS Method

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 class 3 solvent ethanol limited to max. 3.0 %.

Re-evaluation date: 4 years from manufacturing date

valid as of 2013-06-01