



Product Specification

Product group: Superdisintegrants
 Brand name: Primojel®
 Article code: 743736
 Product description: Sodium Starch Glycolate
 Document No.: PD-0046 Page 1 of 2

Production site: DFE Pharma BV, Foxhol, The Netherlands.
 Product name: Primojel® Conforms to USP - NF, Ph.Eur, JP monograph, current at time of manufacture.
 Product description: Fine, white or almost white, free-flowing powder.
 Residual Solvents
 (CPMP/ICH/283/9): No Class 1, 2, 3 and other solvents than ethanol and water are used during production.
 Identification: Complies with Pharmacopoeia when tested.

Physical-Chemical data:

Loss on drying
 pH
 Sodium content (chemically linked)
 Sodium glycolate content
 Sodium chloride content
 Alcohol soluble material
 Gelvolume
 Iron (Fe)
 Heavy metals
 Ethanol content (class 3 solvent)
 Appearance of solution
 Nitrite content (ppm)

Specification

max. 10.0 %
 5.5 - 7.5
 2.8 - 4.2 %
 max. 2.0 %
 max. 5.5 %
 max. 15.0 %
 45 – 82 ml
 max. 20 mg/kg
 max. 20 mg/kg
 max. 6.0 %
 passes test
 reported value

Microbiological data:

Total aerobic mesophilic count
 Yeasts and Moulds
 Candida albicans
 Pseudomonas aeruginosa
 Staphylococcus aureus
 Escherichia coli
 Salmonella
 Bile-tolerant gram-negative bacteria

Specification

max. 100 cfu/g
 max. 50 cfu/g
 negative in 1 g
 negative in 10 g
 negative in 10 g
 negative in 10 g
 negative in 10 g
 negative in 10 g

Particle size (Airjet sieve analysis, Alpine)

Particle size distribution % <63 µm
 Particle size distribution % <125 µm

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min. 93 %
 min. 100 %



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Storage:

Keep in original, unopened packing and away from strongly odorous materials
Store at room temperature (normal warehouse conditions), allowing temporary excursions.

This document substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature : 

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