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:	**Specification**
Loss on drying	max. 10.0 %
pH	5.5 - 7.5
Sodium content (chemically linked)	2.8 - 4.2 %
Sodium glycolate content	max. 2.0 %
Sodium chloride content	max. 5.5 %
Alcohol soluble material	max. 15.0 %
Gelvolume	45 – 82 ml
Iron (Fe)	max. 20 mg/kg
Heavy metals	max. 20 mg/kg
Ethanol content (class 3 solvent)	max. 6.0 %
Appearance of solution	passes test
Nitrite content (ppm)	reported value

Microbiological data:	**Specification**
Total aerobic mesophilic count	max. 100 cfu/g
Yeasts and Moulds	max. 50 cfu/g
Candida albicans	negative in 1 g
Pseudomonas aeruginosa	negative in 10 g
Staphylococcus aureus	negative in 10 g
Escherichia coli	negative in 10 g
Salmonella	negative in 10 g
Bile-tolerant gram-negative bacteria	negative in 10 g

Particle size (Airjet sieve analysis, Alpine)	**Specification**
Particle size distribution % <63 µm	min. 93 %
Particle size distribution % <125 µm	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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