



# Product Specification

Product group: Superdisintegrants  
 Brand name: Primojel®  
 Article code: 743736  
 Product description: Sodium Starch Glycolate  
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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

## **Specification**

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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