



Product Specification

Product group: Superdisintegrants
 Brand name: Primellose®
 Article code: 743737
 Product description: Croscarmellose Sodium
 Document No.: PD-0047 Page 1 of 2

Production site: DFE Pharma BV, Foxhol, The Netherlands
 Product name: Primellose® conforms to USP-NF, Ph.Eur., JP monograph, current at time of manufacture
 Product description: White or greyish-white, hygroscopic 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
 Sodium glycolate and sodium chloride content
 Content of water-soluble material
 pH
 Degree of substitution
 Settling volume
 Residue on ignition/Sulphated ash
 Heavy metals
 Ethanol (class 3 solvent)
 Nitrite content (ppm)

Specification

max. 7.0 %
 max. 0.5 %
 1.0 – 10.0 %
 5.0 - 7.0
 0.60 - 0.85
 10.0 - 30.0 ml
 14.0 - 28.0 %
 max. 10 mg/kg
 max. 6.0 %
 reported value

Microbiological data:

Total aerobic microbial count
 Yeasts and Moulds
 Escherichia coli
 Staphylococcus aureus
 Pseudomonas aeruginosa
 Candida albicans
 Salmonella

Specification

max. 100 cfu/g
 max. 20 cfu/g
 negative in 10 g
 negative in 10 g
 negative in 10 g
 negative in 1 g
 negative in 10 g

Particle size (Airjet sieve analysis, Alpine)

Particle size distribution % <45 µm
 Particle size distribution % <75 µm
 Particle size distribution % <125 µm

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65 - 85 %
 min. 90 %
 min. 98 %



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Storage:

Keep in original, unopened packing and away from strongly odorous materials
Temperature averaging between 5 and 25 °C, relative humidity of max. 70%.

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 :

A handwritten signature in blue ink that reads 'B. Dickhoff'.

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.