Product Specification

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

Production site: DFE Pharma BV, Foxhol, The Netherlands
Product name: Primellose® conforms to USP-NF, Ph.Eur., JP, ChP 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:	**Specification**
Loss on drying	max. 7.0 %
Sodium glycolate and sodium chloride content	max. 0.5 %
Content of water-soluble material	1.0 – 10.0 %
pH	5.0 - 7.0
Degree of substitution	0.60 - 0.85
Settling volume	10.0 - 30.0 ml
Residue on ignition/Sulphated ash	14.0 - 28.0 %
Heavy metals	max. 10 mg/kg
Ethanol (class 3 solvent)	max. 6.0 %
Nitrite content (ppm)	reported value

Microbiological data:	**Specification**
Total aerobic microbial count	max. 100 cfu/g
Yeasts and Moulds	max. 20 cfu/g
Escherichia coli	negative in 10 g
Staphylococcus aureus	negative in 10 g
Pseudomonas aeruginosa	negative in 10 g
Candida albicans	negative in 1 g
Salmonella	negative in 10 g

Particle size (Airjet sieve analysis, Alpine)	**Specification**
Particle size distribution % <45 µm	65 - 85 %
Particle size distribution % <75 µm	min. 90 %
Particle size distribution % <125 µm	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 : 

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