



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, 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:

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

Specification

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

Specification

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



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

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 appears to read 'B. Dickhoff'.

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