



PHARMATRANS SANAQ AG

PHARMACEUTICALS

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SPECIFICATIONS

Microcrystalline Cellulose MCC SANAQ[®]

Type	101	102	200	301	302	UL-002	Test method
Description	Microcrystalline Cellulose is purified, partially depolymerized cellulose prepared by treating alpha cellulose, obtained as a pulp from fibrous plant material, with mineral acids.						
Appearance	White to almost white, fine or granular powder						
Odour	odourless						
Solubility	Practical insoluble in water, absolute ethanol, acetone and toluene						Pharm. Eur.
Iodinated zink chloride solution (Ident. A)	passes						USP-NF/Ph. Eur.
Degree of Polymerization (Ident. B)	n.m.t. 350 DP units						USP-NF/Ph. Eur.
Particle Size							PTS Standard
+ 60 mesh	n.m.t. 1.0 %	n.m.t. 8 %	n.l.t. 10.0 %	n.m.t. 1.0%	n.m.t. 8.0%	l.t. 0.5%	
+ 100 mesh			n.l.t. 50.0 %			l.t. 5.0%	
+ 200 mesh	n.m.t. 30.0%	n.l.t. 45.0 %		n.m.t. 30.0%	n.l.t. 45%	l.t. 5-30%	
Average Particle Size	50 µm	100 µm	180 µm	50 µm	100 µm	50 µm	
Bulk density g/cm ³	0.26 - 0.31	0.28 - 0.33	0.29 - 0.36	0.34 - 0.45	0.35 -0.46	0.13 - 0.23	USP-NF
pH value	5.0 - 7.0						USP-NF/Ph. Eur.
Conductivity	n.m.t. 75 µ S						USP-NF
Loss on drying	n.m.t. 7.0 %						USP-NF/Ph. Eur.
Sulphate Ash /Residue on ignition	n.m.t. 0.05 %						USP-NF
Water soluble substances	n.m.t. 0.24 %						USP-NF/Ph. Eur.
Ether soluble substances	n.m.t. 0.05 %						USP-NF/Ph. Eur.
Heavy metals	n.m.t. 0.001 %						USP-NF/Ph. Eur.
Organic volatile impurities	to meet current N.F.						USP-NF
Starch	negative						Pharm. Eur.

The MCC SANAQ[®] has not come into contact with any organic solvents during the production, storage and delivery.

Microbiological Parameters

Total aerobic count	n.m.t. 1000 CFU/g	USP-NF / Ph. Eur.
Moulds and yeasts	n.m.t. 100 CFU/g	USP-NF / Ph. Eur.
E. coli, Pseudomonas aeruginosa	negative in 10 g sample	USP/Ph. Eur.
St. Aureus, Salmonella species	negative in 10 g sample	USP/Ph. Eur.