

Quality control Specifications

Product: Microcrystalline cellulose Sphere

Grade: Cellurasphere 1000

Description: White, nearly white or beige, hard and almost spherical particles, practically insoluble in water and most of the organic solvents, soluble in NaOH (1 in 20 Parts)

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Odor Odorless

Pharmacopeial tests

Identification A (USP/BP), B(EP), JP, (Zinc chloride Test)

Identification A (EP)

Identification B (USP/BP), JP, C (EP)

Degree of polymerization

Identification 2 (JP)

Solubility (Coppertetramine solution)

pH

Conductivity

Water-soluble substances

Ether-Soluble substances

Loss on Drying

Heavy Metals

Residue on Ignition/Sulphated Ash

Specifications

Correspond as NF, EP, JP

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NMT 350 as USP/NF, NF, EP, JP

Corresponds as JP

Corresponds as NF, EP, JP

5.0 -7.0 as NF, EP, JP

NMT 75 μ S.cm⁻¹ as NF, EP, JP

NMT 0.25 % as NF, EP, JP

NMT 0.05 % as NF, EP, JP

NMT 7 % as NF, EP, JP

NMT 10 ppm NF, EP, JP

NMT 0.1 % as NF, EP, JP

Standards

Bulk Density

Assay

Particle size

Sphericity degree (average)

Friability (%)

Swelling index (ml/g)

Inhouse specifications

0.6 to 1.0 g/ml

97 - 102 %

1000-1400 μ

NLT 90 %

0

NMT 2

Microbial Limits

TVAC (Total Viable aerobic count) NMT 1000 cfu/g as NF, EP, JP

TYMC (Total yeast and mould Count) NMT 100 cfu/g as NF, EP, JP

S. Aureus Absent as NF, EP, JP

E. Coli Absent as NF, EP, JP

P. Aeruginosa Absent as NF, EP, JP

Salmonella Species Absent as NF, EP, JP

The Raw materials processing and product do not contain any solvent listed in organic volatile impurities (USP<467>) and residual Solvents (Ph.Eur <5.4>)

Storage: Store in well closed and tight container and protect from light.