

Quality control Specifications

Product: Microcrystalline cellulose Sphere

Grade: Cellurasphere 100

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

100-200 μ

NLT 90 %

0

NMT 2

Microbial Limits

TVAC (Total Viable aerobic count)

TYMC (Total yeast and mould Count)

S. Aureus

E. Coli

P. Aeruginosa

Salmonella Species

NMT 1000 cfu/g as NF, EP, JP

NMT 100 cfu/g as NF, EP, JP

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.