

Quality control Specifications

Product: Microcrystalline cellulose Sphere

Grade: Cellurasphere 350

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 %

355-500 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

Absent as NF, EP, JP

Absent 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.