

BaseBulk

CERTIFICATE OF ANALYSIS

Product	MICROCRYSTALLINE CELLULOSE USP/EP
Grade	ACCEL 200
MOA	USP/NF, JP, Ph. Eur., BP
Batch No.	D105230381
Mfg. Date	May/2023
Re-evaluation date	April/2028
Description	White or almost white, fine or granular powder. Practically insoluble in water, dilute acid and most of organic solvents, slightly soluble in dilute NaOH solution.

Pharmacopoeial Test Items

Test Item	Batch Results	Specification
Identification A (Zinc Chloride test)	Passes	Have to correspond as USP/NF,JP,Ph.Eur.,BP
Identification B (Degree of Polymerization)	Complies	NMT 350 as USP/NF,JP,Ph.Eur.,BP
Solubility (coppertetramine solution)	Complies	Have to correspond as Ph., Eur.,BP
pH	6.69	5.0-7.5 as USP/NF,JP,Ph.Eur.,BP
Conductivity	48 $\mu\text{S}\cdot\text{cm}^{-1}$	NMT 75 $\mu\text{S}\cdot\text{cm}^{-1}$ as USP/NF,JP,Ph.Eur.,BP
Water - Soluble Substance	0.1298 %	NMT 0.25% as USP/NF,JP,Ph.Eur.,BP
Ether - Soluble Substance	0.0253 %	NMT 0.05% as USP/NF,JP,Ph.Eur.,BP
Loss on Drying	3.692 %	NMT 7.0% as USP/NF,JP,Ph.Eur.,BP
Heavy metals	Complies	NMT 10 ppm as USP/NF,JP,Ph.Eur.,BP
Residue on Ignition / Sulphated Ash	0.0292 %	NMT 0.1% as USP/NF,JP,Ph.Eur.,BP

Standards

Test Item	Batch Results	In house Specification
Bulk Density	0.3280 g/ml	0.31 to 0.39 g/ml
Assay (Dried)	99.63 %	97.0% to 102.0%
Sieve Analysis (% Retention)60 Mesh	17.88 %	≥ 10.0%
Sieve Analysis (% Retention)100 Mesh	65.52 %	≥ 50.0%
Particle Size Distribution D ₁₀	55 μ	≤ 70 μ
Particle Size Distribution D ₅₀	188 μ	150 – 200 μ
Particle Size Distribution D ₉₀	320 μ	≥ 260 μ

Microbial Limits

Test Item	Batch Results	Specification
Total Viable Aerobic Count	Complies	N.M.T. 1000cfu/g as USP/NF,JP,Ph.Eur.,BP
Total yeast & Mould Count	Complies	N.M.T. 100cfu/g as USP/NF,JP,Ph.Eur.,BP
Staphylococcus aureus	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Escherichia Coli.	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Pseudomonas aeruginosa	Complies	Absent as USP/NF,JP,Ph.Eur.,BP
Salmonella species	Complies	Absent as USP/NF,JP,Ph.Eur.,BP

The raw materials, manufacturing process, and product do not contain any of solvents listed in Organic Volatile Impurities (USP<467>) & residual solvents (Ph. – Eur<5.4>).

Storage recommendation: Preserve in tight containers.