BaseBulk

CERTIFICATE OF ANALYSIS

Product Name	Microcrystalline Cellulose USP/EP
Grade	ACCEL 102
Batch Number	D103250260
Mfg. Date	03/2025
Re-evaluation Date	February 2030
Description	White or almost white, fine or granular powder. Practically insoluble in water, dilute acid and most organic solvents, slightly soluble in dilute NaOH solution.

Pharmacopoeial Test Items

Test Item	Specification	Result
Identification A (Zinc Chloride test)	Corresponds to USP/NF, JP, Ph. Eur., BP	Passes
Identification B (Degree of Polymerization)	NMT 350 as USP/NF, Ph.Eur., BP	Complies
Solubility (coppertetramine solution)	Have to correspond Ph.Eur., BP	Complies
pH	5.0–7.5 as USP/NF, Ph.Eur., BP	6.51
Conductivity	NMT 75 µS/cm as USP/NF, Ph.Eur., BP	52 µS/cm
Water-Soluble Substance	NMT 0.25% as USP/NF, Ph.Eur., BP	0.1486%
Ether-Soluble Substance	NMT 0.05% as USP/NF, Ph.Eur., BP	0.0282%
Loss on Drying	NMT 7.0% as USP/NF, Ph.Eur., BP	3.501%
Heavy Metals	NMT 10 ppm as USP/NF, Ph.Eur., BP	Complies
Residue on Ignition / Sulphated Ash	NMT 0.1% as USP/NF, Ph.Eur., BP	0.0315%

Standards

Test Item	Specification	Result
Bulk Density	0.26–0.34 g/ml	0.2908 g/ml
Assay (Dried)	97.0–102.0%	99.50%
Sieve Analysis (60 Mesh)	≤8.0%	1.01%
Sieve Analysis (200 Mesh)	≥45.0%	58.49%
Particle Size Distribution D_{10}	≤45 µ	26 µ
Particle Size Distribution D_{50}	70-100	98 µ
Particle Size Distribution D_{90}	≥140 µ	209 µ

Microbial Limits

Test Item	Specification	Result
Total Viable Aerobic Count	NMT 1000 cfu/g as USP/NF, Ph.Eur., BP	Complies
Total Yeast & Mould Count	NMT 100 cfu/g as USP/NF, Ph.Eur., BP	Complies
Staphylococcus aureus	Absent as USP/NF, Ph.Eur., BP	Complies
Escherichia coli	Absent as USP/NF, Ph.Eur., BP	Complies
Pseudomonas aeruginosa	Absent as USP/NF, Ph.Eur., BP	Complies
Salmonella species	Absent as USP/NF, Ph.Eur., BP	Complies

The raw materials, manufacturing process, and product do not contain any solvents listed in Organic Volatile Impurities (USP<467>) & residual solvents (Ph. Eur. <5.4>).
Storage recommendation: Preserve in tight containers.