

SPECIFICATION

Product Name: Microcrystalline Cellulose-101 BP Grade
Chemical Formula: $(C_6H_{10}O_5)_n$
CAS Number: 9004-34-6
Molecular Weight: 30,000 – 50,000 g/mol
Appearance: White or almost white fine powder
Odor: Odorless.

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min/Max)
Identification			
Test – (A) By IR	-	Complies	The sample spectrum should be concordant with that of the reference spectrum.
Test – (B) By Chemical	-	Complies	The substance becomes should be violet-blue.
Test – (C) The degree of polymerization	-	Complies	The degree of polymerization should not be more than 350.
PH of solution (5.0 g with 40 ml CO ₂ free water)	-	6.00	5.0 to 7.5
Conductivity	$\mu S.cm^{-1}$	48 $\mu S.cm^{-1}$	The conductivity of the solution should be does not exceed the conductivity of the water by more than 75 $\mu S.cm^{-1}$
Ether- soluble substances	%	0.02%	Max. 0.5%
Water-soluble substances	%	0.14%	Max. 0.20%
Arsenic	PPM	Complies	NMT 2 PPM
Heavy Metals	PPM	Complies	Max. 10 PPM
Loss on drying (at 105°C for 3 h)	%	3.20%	Max. 6.0%

Sulphated ash (Calculated on dry basis)	%	0.06%	Max. 0.10%
Assay (Dried basis)	%	99.75%	NLT 97.0% and NMT 102.0% of cellulose
Bulk Density (Untapped)	g/cm ³	0.30 g/cm ³	0.25 to 0.40 g/cm ³
Sieve analysis (% Retention by sieve shaker)	%	0.00%	60 Mesh- NMT 1.0%
	%	18.80%	200 Mesh- NMT 30.0%
Microbial Test			
Total aerobic microbial count	cfu/g	Complies	NMT 1000 cfu/g
Total Yeast and Molds count	cfu/g	Complies	NMT 100 cfu/g
Escherichia coli & salmonella	Absent	Absent	Should be absent
Pseudomonas aeruginosa	Absent	Absent	Should be absent
Staphylococcus aureus	Absent	Absent	Should be absent

Physical Properties

- Solubility: Practically insoluble in water. Insoluble in ethanol. Insoluble in acetone. Insoluble in ether.

Shelf Life & Storage

- Shelf Life: 5 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a tightly closed container in a cool, dry, and well-ventilated place, protected from moisture, humidity, and contamination. Keep the container tightly sealed when not in use to preserve its physical properties.

Applications

- Use: Widely used as a binder, diluent, filler, disintegrant, and compression aid in pharmaceutical, nutraceutical, food, and cosmetic formulations.
- Dosage: Depends on Intended function (binder, filler, disintegrant, etc.), Type of dosage form (tablet, capsule, powder), Active ingredient properties, Desired tablet hardness and disintegration time, Manufacturing process and regulatory requirements.

Packaging

- Standard Packing: 25 kg woven PP bags with inner liner or as per customer requirement.

-Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.

* Specifications are based on the manufacturer's provided specifications.

