IngredientDepot

Updated June 13th, 2020

Certificate of Analysis / Certificat D'Analyse

MCC 101

Microcrystalline Cellulose, Ph. Eur., NF

MCC 101

Cellulose Microcristalline, Ph. Eur., NF

Manufacturer: North American

GENERAL DESCRIPTION	
DESCRIPTION	**SPECIFICATION**
Appearance	White or almost white, fine or granular powder.
Solubility	Practically insoluble in water, acetone, anhydrous ethanol and toluene, dilute acids and sodium hydroxide solution (50 g/L)

CHARACTERISTICS	ACCEPTANCE CRITERIA	REFERENCE
Identification A	Violet-blue color	Ph. Eur., NF
Identification B	Degree of polymerization max. 350	Ph. Eur., NF
Conductivity	Max. 75 µS/ cm	Ph. Eur., USP
Ether-soluble substances	Max. 0.05%	Ph. Eur., NF
Heavy Metals	Max. 10 ppm	USP
Loss on drying	Max. 6.0%	Ph. Eur., USP
pH	5.0 - 7.0	Ph. Eur., USP
Solubility	Completely dissolves	Ph. Eur.
Sulphated ash / residue on ignition	Max. 0.05%	Ph. Eur., USP
Water-soluble substances	Max. 0.24%	Ph. Eur., NF
TAMC (Total aerobic microbial count)	10^2 cfu/g	Ph. Eur., USP
TYMC (Total yeasts and molds)	20 cfu/g	Ph. Eur., USP
Escherichia coli	Absent in 1 g	Ph. Eur., USP
Pseudomonas aeruginosa	Absent in 1 g	Ph. Eur., USP
Salmonella species	Absent in 10 g	Ph. Eur., USP
Staphylococcus aureus	Absent in 1 g	Ph. Eur., USP
Bulk density	0.26 - 0.35 g/mL	USP
Particle size (retained on sieve)		Manufacturer
> 250 µm (60 mesh)	Max. 1 %	
> 75 µm (200 mesh)	Max. 30 %	

*The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur.<5.4>, USP<467>).

* Data based on manufacturer's document

Quality Control