

Certificate of Analysis / Certificat D'Analyse

VIVAPUR MCC 102

Microcrystalline Cellulose, Ph. Eur., NF, JP, FCC

VIVAPUR MCC 102

Cellulose Microcristalline, Ph. Eur., NF, JP, FCC

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

CHARACTERISTICS	ACCEPTANCE CRITERIA	BATCH RESULT	REFERENCE
Identification A	IR scan conforms	Passes*	Ph. Eur., NF
Identification B, (1)	Violet-blue color	Passes	Ph. Eur., NF, JP
Identification C, (3)	Degree of polymerization max.350	251	Ph. Eur., NF, JP
Identification (2)	Stable suspension	Passes*	JP
Conductivity	Max. 50µS/cm	24 µS/cm	Ph. Eur., NF, JP
Ether-soluble substances	Max. 0.05%	< 0.05 % *	Ph. Eur., NF, JP
Heavy Metals	Max. 10 ppm	< 10 ppm *	Manufacturer
Loss on drying	Max. 7.0%	3.9 %	Ph. Eur., USP, JP
pH	5.0 - 7.0	6.4	Ph. Eur., USP, JP
Solubility	Dissolves completely	Passes *	Ph. Eur.
Sulphated ash / residue on ignition	Max. 0.05%	< 0.05 % *	Ph. Eur., USP, JP
Water-soluble substances	Max. 0.24%	0.10 %	Ph. Eur., NF, JP
TAMC (Total aerobic microbial count)	10 ² cfu/g	Passes *	Ph. Eur., USP, JP
TYMC (Total yeasts and molds)	20 cfu/g	Passes *	Ph. Eur., USP, JP
Escherichia coli	Absent in 1 g	Absent *	Ph. Eur., USP, JP
Pseudomonas aeruginosa	Absent in 1 g	Absent *	Ph. Eur., USP, JP
Salmonella species	Absent in 10 g	Absent *	Ph. Eur., USP, JP
Staphylococcus aureus	Absent in 1 g	Absent *	Ph. Eur., USP, JP
Bulk density	0.28 – 0.33 g/mL	0.30 g/mL	NF, JP
Particle size (retained on air jet sleeve)			Manufacturer
> 250 µm (600 mesh)	Max. 8%	1 %	Manufacturer
> 75 µm (200 mesh)	Max. 45%	61 %	Manufacturer
> 320 µm (32 mesh)	Min. 70%	89 %	Manufacturer
Particle size (laser diffraction)	d ₁₀ 20 - 50 µm	36 µm	Manufacturer
	d ₅₀ 90 - 150 µm	123 µm	Manufacturer
	d ₉₀ 190 - 300 µm	268 µm	Manufacturer
TUP ¹	Max. 9/ 600 cm ²		Manufacturer

¹Technically unavoidable particles according to IPEC TUPP guideline (i.e. dark particles).

*Results reported are expected results based on periodic testing.

* Data based on manufacturer's document

John

Quality Control

