

MICROCEL

MICROCRYSTALLINE CELLULOSE



CERTIFICATE OF ANALYSIS



TYPE: MC-12

LOT:

ANALYSIS	SPECIFICATIONS	RESULTS	METHODS
Appearance	White, non fibrous powder, odorless	Pass	IQ-10-101
Loss on drying %	Not more than 7.0	3.2	USP/NF/EP
pH	5.0 to 7.0	6.3	USP/NF/EP
Identification A	Positive	Positive	USP/NF/EP
Identification B (degree of polymerization)	Not more than 350	265	USP/NF/EP
Water soluble substances %	Not more than 0.24	0.19	USP/NF/EP
Residue on ignition (sulphated ash) %	Not more than 0.05	0.04	USP/NF/EP
Heavy metals ppm	Not more than 10	Pass	USP/NF
Ether soluble substances %	Not more than 0.05	0.00	USP/NF/EP
Solubility in copper tetramine	Positive	Positive	EP
Conductivity uS	Not more than 75	41	USP/NF/EP
Bulk density g/cm ³	0.30 to 0.40	0.34	USP/NF
Retained 60 mesh (250 microns) %	Not less than 10.0	14.6	IQ-10-118
Retained 100 mesh (150 microns) %	Not less than 40.0	48.4	IQ-10-118

This product is manufactured in accordance with the Good Manufacturing Practices and complies with USP39/NF34, EP9ed. specifications.

Solubility: Practically insoluble in sodium hydroxide solution (1 in 20); insoluble in water, in dilute acids, and in most organic solvents.

Conforms with Blanver Microbiological Specifications: Total Aerobic Microbial Count - NMT 1000 cfu per gram, Total Combined Molds and Yeasts Count - NMT 100 cfu per gram, absence in a 10 gram sample - Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Salmonella species - USP <61> and <62>.

This product meets the requirement for Residual Solvents - USP <467> / EP <5.4>. No solvents are used in the manufacturing process.

Manufacturing site: Blanver, Itapevi Unit - Brazil.

Manufacturing Date: 30/jan/2017

Re-Evaluation Date: 30/jan/2020

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Carla Nogueira
Quality Control

BLANVER FARMOQUÍMICA E FARMACÉUTICA S.A.

Rua Dr. José Alexandre Crosnag, 715 - CEP: 06680-035 - Itapevi - SP - Fone: 55 11 4144-9400 - E-mail: blanver@blanver.com