

239644

MICROCEL

MICROCRYSTALLINE CELLULOSE



CERTIFICATE OF ANALYSIS

TYPE: MC-101

LOT:

ANALYSIS	SPECIFICATIONS	RESULTS	METHODS
Appearance	White, non fibrous powder, odorless	Pass	IQ-10-101
Loss on drying %	Not more than 7.0	3.3	USP/NF/EP
pH	5.0 to 7.0	6.1	USP/NF/EP
Identification A	Positive	Positive	USP/NF/EP
Identification B (degree of polymerization)	Not more than 350	273	USP/NF/EP
Water soluble substances %	Not more than 0.24	0.17	USP/NF/EP
Residue on ignition (sulphated ash) %	Not more than 0.05	0.01	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	31	USP/NF/EP
Bulk density g/cm3	0.26 to 0.31	0.28	USP/NF
Retained 60 mesh (250 microns) %	Not more than 1.0	0.0	IQ-10-118
Retained 200 mesh (75 microns) %	Not more than 30.0	26.5	IQ-10-118

This product is manufactured in accordance with the Good Manufacturing Practices and complies with USP40/NF35, EP9ed. specifications.
 Solubility: Practically insoluble in sodium hydroxide solution (1 in 20); insoluble in water, in dilute acids, and in most organic solvents.
 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 for Salmonella species and absence in a 1 gram sample for Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus - 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: Itacel, Itapevi Unit - Brazil.

Manufacturing Date: 24/aug/2017
 Re-Evaluation Date: 24/aug/2020
 Printed Date: 01/sep/2017
 Issuing Date: 01/sep/2017

Mauro Witzel
Quality Control

ITACEL FARMACÊUTICA LTDA.

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CERTIFICATE OF ANALYSIS

TYPE: MC-101

LOT:

ANALYSIS	SPECIFICATIONS	RESULTS	METHODS
Appearance	White, non fibrous powder, odorless	Pass	IQ-10-101
Loss on drying %	Not more than 7.0	3.6	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	273	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	0.01	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 tetrammine	Positive	Positive	EP
Conductivity uS	Not more than 75	28	USP/NF/EP
Bulk density g/cm3	0.26 to 0.31	0.26	USP/NF
Retained 60 mesh (250 microns) %	Not more than 1.0	0.0	IQ-10-118
Retained 200 mesh (75 microns) %	Not more than 30.0	23.6	IQ-10-118

This product is manufactured in accordance with the Good Manufacturing Practices and complies with USP40/NF35, EP9ed. specifications.

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

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