

CERTIFICATE OF ANALYSIS

SMCC 90 - Silicified Microcrystalline Cellulose NF

composed of

(Microcrystalline Cellulose, NF, Ph. Eur., JP, and Colloidal Silicon Dioxide, NF, Silica, Colloidal Anhydrous, Ph. Eur., Light Anhydrous Silicic Acid, JP)

Characteristics:	Specifications:	References:
Degree of polymerization	Not more than 350	NF, Ph. Eur., JP
Particle size (air jet)	Not more than 8.0% retained on #60 mesh sieve (250 µm) 45.0 - 80.0% retained on #200 mesh sieve (75 µm)	Pharma Method
Particle size by laser diffraction	d ₁₀ 25 - 46 µm d ₅₀ 98 - 146 µm d ₉₀ 195 - 276 µm	Pharma Method
Water-soluble substances	Not more than 0.24%	NF, Ph. Eur., JP
Ether-soluble substances	Not more than 0.05%	NF, Ph. Eur., JP
Heavy metals	Not more than 0.001%	USP, Ph. Eur., JP
Solubility in ammoniacal copper tetrammine solution	Completely dissolves	Ph. Eur.
Escherichia coli	Absent in 10 g	USP, Ph. Eur., JP
Pseudomonas aeruginosa	Absent in 10 g	USP, Ph. Eur., JP
Salmonella species	Absent in 10 g	USP, Ph. Eur., JP
Staphylococcus aureus	Absent in 10 g	USP, Ph. Eur., JP
Identification V	Stable suspension	JP
Residual solvents	Meets the requirements	USP, Ph. Eur.
Tapped density	0.37 - 0.50 g/mL	Pharma Method

* Data based on manufacturer's document

Jmk

Quality Control

