JRS PHARMA & GUJARAT MICROWAX PRIVATE LIMITED

A MEMBER OF THE JRS GROUP

R#15780
R10178
1-23-23

(Unit IV)

FLOCEL® 102 Plus

Microcrystalline Cellulose, Ph. Eur. NF, E 460 (i), FCC

CERTIFICATE OF ANALYSIS

C2C nutra

Batch No.: FB2203047
Re-evaluation date: March-2027
Manufacturing date: March-2022

Manufacturing site: Chandarda, india

Description
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	Violet-blue color	Passes	Ph. Eur., NF
Identification C	Degree of polymerization max. 350	218	Ph. Eur., NF
Conductivity	Max. 75 µS/ cm	45 µS/ cm	Ph. Eur., NF
Arsenic	Max. 2 ppm	< 2 ppm	IP
Heavy metals	Max. 10 ppm	< 10 ppm	JRS Method
Ether-soluble substances	Max. 0.05 %	0.01 %	Ph. Eur., NF
Loss on drying	Max. 7.0 %	4.1 %	Ph. Eur., USP
pH	5.5 - 7.0	6.2	Ph. Eur., USP
Solubility	Dissolves completely	Passes	Ph. Eur.
Starch and dextrins	Passes	Passes	IP
Organic impurities	Passes	Passes	IP
Assay	97.0 - 102.0 %	99.7 %	IP
Sulphated ash / residue on ignition	Max. 0.05 %	< 0.05 %	Ph. Eur., USP
Water-soluble substances	Max. 0.24 %	0.11 %	Ph. Eur., NF
TAMC (Total Aerobic Microbial Count)	Max. 10^2 cfu/ g	30 cfu/ g	Ph. Eur., USP
TYMC (Total Yeast and Mold Count)	Max. 20 cfu/ g	< 10 cfu/ g	Ph. Eur., USP
Escherichia coli	Absent in 1 g	Absent	Ph. Eur., USP
Pseudomonas aeruginosa	Absent in 1 g	Absent	Ph. Eur., USP
Salmonella species	Absent in 10 g	Absent	Ph. Eur., USP
Staphylococcus aureus	Absent in 1 g	Absent	Ph. Eur., USP
Bulk density	0.28 - 0.35 g/mL	0.30 g/mL	NF
Particle size (retained on air jet sieve)			JRS Method
> 250 µm (60 mesh)	Max. 8.0 %	1.1 %	
> 75 µm (200 mesh)	45.0 - 70.0 %	53.2 %	
Particle size distribution (laser diffraction)			JRS Method
d10	Max. 50 µm	36 µm	
d50	90 - 140 µm	124 µm	
d90	Min. 170 µm	264 µm	
Technical unavoidable particles (TUP)	Max. 8 / 600 cm^2	4 / 600 cm^2	JRS Method

The batch described by this certificate meets the requirements of Ph. Eur. and NF monographs for "Microcrystalline Cellulose" current edition, it complies with E 460 (i) monograph (231/2012), FCC and all relevant EU Food Regulations. It is released on the basis of the results ascertained. **FLOCEL** is manufactured under GMP for excipients according to IPEC and USP <1078>.

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

Elements listed in ICH Q3D Guideline for elemental impurities are not used in manufacturing and not analyzed per batch; detailed information is available on request.

Storage recommendation: Protect from excessive heat and moisture. Keep containers closed.

For JRS PHARMA & GUJARAT MICROWAX PVT. LTD. UNIT IV

Chemist Quality Control / Anil Patel

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