



(Formerly known as GUJARAT MICROWAX PVT. LTD.)

FLOCEL 102

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

CERTIFICATE OF ANALYSIS

Batch-no.: L0143 Manufacturing site: Nandasan, India
 Re-evaluation date: April-2024
 Manufacturing date: April-2019

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

Identification A
 Identification B
 Identification C
 Conductivity
 Ether-soluble substances
 Heavy metals
 Loss on drying
 pH
 Solubility
 Sulphated ash / residue on ignition
 Water-soluble substances
 TAMC (Total aerobic microbial count)
 TYMC (Total yeast and mold count)
 Escherichia coli
 Pseudomonas aeruginosa
 Salmonella species
 Staphylococcus aureus
 Bulk density
 Sieve Analysis (% Retention)
 > 250 µm (60 mesh)
 > 75 µm (200 mesh)

Acceptance criteria

IR scan conforms
 Violet-blue color
 Degree of polymerization max. 350
 Max. 75 µS/cm
 Max. 0.05 %
 Max. 10 ppm
 Max. 6.0 %
 5.0 - 7.0
 Dissolves completely
 Max 0.05 %
 Max. 0.24 %
 Max. 10² CFU/g
 Max. 20 CFU/g
 Absent in 1 g
 Absent in 1 g
 Absent in 10 g
 Absent in 1 g
 0.27 - 0.34 g/mL
 < 8.0 %
 > 45.0 %

Batch result

Passes
 Passes
 Passes
 42 µS/cm
 0.01%
 < 10 ppm
 4.18%
 6.55
 Passes
 0.02%
 0.12%
 35 CFU/g
 < 10 CFU/g
 Absent
 Absent
 Absent
 Absent
 0.30 g/mL
 2.41%
 57.62%

Reference

Ph. Eur., NF
 Ph. Eur., NF
 Ph. Eur., NF
 Ph. Eur., USP
 Ph. Eur., NF
 JRS Method
 Ph. Eur., USP
 Ph. Eur., USP
 Ph. Eur., USP
 Ph. Eur., USP
 Ph. Eur., USP
 Ph. Eur., USP
 USP
 JRS Method

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.

For JRS PHARMA & GUJARAT MICROWAX PVT. LTD.

Chemist Quality Control / Anil Patel

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