

VIVAPUR® 112,

Microcrystalline Cellulose Ph. Eur., NF, JP, E460 (i), FCC

Specification

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, (2)
 Identification B, (1)
 Identification C, (3)

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
 Particle Size (retained on air jet sieve)
 > 250 µm (60 mesh)
 > 75 µm (200 mesh)
 > 32 µm (450 mesh)
 Particle Size (laser diffraction)
 d10
 d50
 d90

TUP¹⁾

Acceptance criteria

IR scan conforms
 Violet-blue color
 Degree of polymerization max. 350

Max. 75 µS/ cm
 Max. 0.05 %
 Max. 10 ppm
 Max. 1.5 %
 5.0 – 7.0
 Dissolves completely
 Max. 0.05 %
 Max. 0.24 %

10² cfu/ g
 20 cfu/ g
 Absent in 1 g
 Absent in 1 g
 Absent in 10 g
 Absent in 1 g

0.30 – 0.36 g/ mL
 Max. 8 %
 Min. 45 %
 Min. 70 %

20 – 50 µm
 90 – 150 µm
 190 – 300 µm

Max. 9/ 600 cm²

Reference

Ph. Eur., NF, JP
 Ph. Eur., NF, JP
 Ph. Eur., NF, JP

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

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

JRS Method

JRS Method

1) Technically unavoidable particles according to IPEC TUPP guideline (i.e. dark particles)

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VIVAPUR 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>, JP<2.46>). 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.

Re-evaluation date: 3 years from manufacturing date

valid as of 2021-08-01