

1-1-2 Yurakucho, Chiyoda-ku, Tokyo 100-0006, JAPAN
 TEL +81-(0)3-6699-3361 FAX +81-(0)3-6699-3467
 Manufacturing site: Ceolus Plant
 304, Mizushiri-machi, Nobeoka-city, Miyazaki 882-0015, JAPAN

SPECIFICATIONS

Compendial name : Microcrystalline Cellulose, NF, Ph.Eur., JPE
Trade name : CELPHERE™
Grade : CP-305

Organic Solvent: not used in our process

Compendial Standards

Description <JPE>
 Identification
 Degree of polymerization
 Loss on drying (%)
 pH
 Residue on ignition (%)
 Water soluble substances (mg)
 Ether soluble substances (mg)
 Heavy metals (ppm)
 Solubility
 Conductivity (μ S/cm)
 Bulk density (g/cm^3)
 Sphere size (%), 106 μ m pass <JPE>
 Total aerobic microbial count (CFU/g)
 Total combined molds and yeasts count (CFU/g)
 Escherichia coli
 Salmonella species
 Pseudomonas Aeruginosa
 Staphylococcus Aureus

Specifications

Passes
 Passes
 100 – 300
 NMT 6.0
 5.0 – 7.5
 NMT 0.1
 NMT 12.5
 NMT 5.0
 NMT 10
 Passes
 NMT 75
 0.80 – 1.15
 NMT 5
 NMT 1000
 NMT 100
 None Present
 None Present
 None Present
 None Present

ASAHI Standards

P.S.D., Asahi method, d10 (μ m) NLT 280
 P.S.D., Asahi method, d50 (μ m) 315 – 475
 P.S.D., Asahi method, d90 (μ m) NMT 500

NMT --- Not More Than JPE --- Japanese Pharmaceutical Excipients

We certify that the product complies with the standards of the NF, Ph. Eur., JPE.

P.S.D., Asahi method: Dynamic image analysis method (by Particle Analyzer CAMSIZER, Retsch Technology)

Storage conditions: Protect from direct sunlight, high temperature and humidity, and store indoors. Avoid transfer of odor or storing in the same place with materials with strong odor.

Re-evaluation Date: Three and a half years after manufacturing, if stored as recommended.

Asahi Kasei Corporation recommends that the customer's quality control unit may re-evaluate the quality of this material at the given time e.g. for loss on drying and extend the shelf life of this lot on its own responsibility.

Yoshinaga Tamura
 General Manager
 Quality Assurance Department
 Functional Additives Division
 Performance Materials SBU