

# ASAHI KASEI CHEMICALS CORPORATION

Hibiya-Mitsui Building 1-2, Yurakucho 1-chome, Chiyoda-ku, TOKYO 100-8440, JAPAN

TEL +81-(0)3-3507-2519 FAX +81-(0)3-3507-2375

Date: August 10, 2007

## SPECIFICATIONS

**Compendial name:** Microcrystalline Cellulose, NF, Ph. Eur., JPE

**Trade name** : Celphere<sup>®</sup>

**Grade** : CP-708

Solvent: not used in our process

### **Compendial Standards**

### **Specifications**

Description <JPE>	Passes
Identification	Passes
Identification, Degree of polymerization	100 - 300
Loss on drying (%)	NMT 6.0
pH	5.5 - 7.0
Residue on ignition (%)	NMT 0.05
Water soluble substances (mg/5g)	NMT 12.5
Water soluble substances (mg/2.5g) <JPE>	NMT 4.0
Ether soluble substances (%)	NMT 0.05
Heavy metals (ppm)	NMT 10
Arsenic (ppm) <JPE>	NMT 2
Starch <JPE>	Passes
Solubility	Passes
Conductivity (μ S/cm)	NMT 75
Bulk density (g/cm <sup>3</sup> )	0.80 - 1.20
Sphere size (%), 106 μ m pass <JPE>	NMT 5
Total aerobic microbial count (cfu/g)	NMT 1000
Total yeast and mold count (cfu/g)	NMT 100
<i>Escherichia coli</i>	None Present
<i>Salmonella</i> species	None Present
<i>Pseudomonas Aeruginosa</i>	None Present
<i>Staphylococcus Aureus</i>	None Present

### **ASAHI Standards**

Sphere size (%)	
710 μ m on 850 μ m pass	NLT 75
850 μ m on	NMT 5
710 μ m pass	NMT 20
500 μ m pass	NMT 1

NMT --Not more than; NLT --Not less than; JPE --Japanese Pharmaceutical Excipients

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

This product meets the requirements for Organic Volatile Impurities of the United States Pharmacopeia <467>.

**Storage conditions:** Store at ambient conditions. Keep containers sealed; material is very hygroscopic.

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

Asahi Kasei Chemicals 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 batch on its own responsibility.

---

Masataka Fujimoto  
General Manager  
CEOLUS Marketing Department  
Functional Additives Division  
Asahi Kasei Chemicals Corporation