

1-105 kanda Jinbocho, Chiyoda-ku, TOKYO 101-8101, JAPAN
 TEL +81-(0)3-3296-3361 FAX +81-(0)3-3296-3467
 Manufacturing site: Sanwa Starch Co., Ltd. (as a subcontractor)
 594, Unate-machi, Kashihara-city, Nara 634-8585, JAPAN

SPECIFICATIONS

Compendial name : Pregelatinized Starch, NF, Ph. Eur., JPE
Grade : PC-10

Botanical Source: Corn

Organic Solvent: not used in our process

Compendial Standards

Specifications

Description	Passes
Identification	Passes
Loss on drying (%)	NMT 13.0
Residue on ignition (%)	NMT 0.5
pH	4.5 - 7.0
Heavy metals (ppm) <JPE>	NMT 20
Arsenic (ppm) <JPE>	NMT 2
Sulfur dioxide (%)	NMT 0.003
Oxidizing substances	Not Detected
Iron (%)	NMT 0.002
Foreign matter. <Ph. Eur.>	Passes
Total aerobic microbial count (CFU/g)	NMT 1000
Total combined molds and yeasts count (CFU/g)	NMT 100
<i>Salmonella</i> species	None Present
<i>Escherichia coli</i>	None Present

NMT --- Not More Than

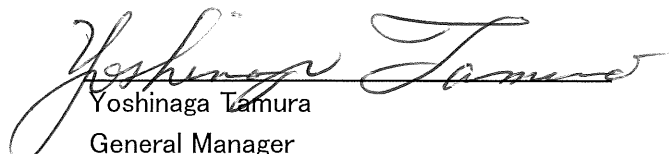
JPE --- Japanese Pharmaceutical Excipients

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

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: Two 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