

Certificate of Analysis

Shin-Etsu Chemical Co., Ltd.
Naoetsu Plant Quality Assurance Department
28-1, Nishifukushima, Kubiki-ku,
Joetsu-shi, Niigata, Japan

Product Name PHARMACOAT
(Hypromellose, USP)
Grade 615
Substitution Type 2910
Viscosity Type 15 mPa·s
Lot Number 1098319
Quantity 1050kg
Manufacture Date 2021/09/03
Recommended Re-Evaluation Date * 2024/09/02
Analysis Date 2021/12/09
Issue No. D5120220301315002-1-01

Remark

This product complies with the specifications described in the current USP, EP and JP.

This product is manufactured in accordance with GMP.

* Shin-Etsu Chemical recommends that the customer's quality control unit may re-evaluate the quality of this material on its own responsibility prior to use after the Recommended Re-Evaluation date.

Storage Conditions: Store containers sealed and in a dry place. Keep away from heat or sunlight.

Test Item	Unit	Test Result	Specification	Method
Description		Conforms	Conforms	JP/USP
Characters		Conforms	Conforms	EP
Identification (1)/A		Conforms	Conforms	JP/USP/EP
Identification (2)/B		Conforms	Conforms	JP/USP/EP
Identification (3)/C		Conforms	Conforms	JP/USP/EP
Identification (4)/D		Conforms	Conforms	JP/USP/EP
Identification (5)/E		Conforms	Conforms	JP/USP/EP
Appearance of solution		Conforms	Conforms	EP
Viscosity	mPa·s	14.6	12.0 - 18.0	JP/USP/EP
pH		6.5	5.0 - 8.0	JP/USP/EP
Heavy metals	ppm	Not more than 20	Not more than 20	JP
Loss on drying	%	1.7	Not more than 5.0	JP/USP/EP
Residue on ignition	%	0.53	Not more than 1.5	JP/USP/EP
Methoxy content	%	28.8	28.0 - 30.0	JP/USP/EP
Hydroxypropoxy content	%	8.8	7.0 - 12.0	JP/USP/EP



K Sato

Kazuomi Sato
General Manager, Q. A. Dept.

Shin-Etsu No. : 72018723-10-01

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Judgment:
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