



CERTIFICATE OF ANALYSIS

Product Name	METOLOSE (Hypromellose, USP)	Lot Number	2115920
Substitution Type	2208	Manufacture Date	2022/11/11
Viscosity Type	15000 mPa·s	Recommended Re-Evaluation Date *	2025/11/10
Analysis Date	2022/11/14	Issue No.	D5120221204614002-1-01
Remark		This product complies with the specifications described in the current USP, EP and JP. This product is manufactured in accordance with GMP.	

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	16700	11250 - 21000	JP/USP/EP
pH		6.7	5.0 - 8.0	JP/USP/EP
Heavy metals	ppm	Not more than 20	Not more than 20	JP
Loss on drying	%	1.2	Not more than 5.0	JP/USP/EP
Residue on ignition	%	0.16	Not more than 1.5	JP/USP/EP
Methoxy content	%	22.6	22.0 - 24.0	JP/USP/EP
Hydroxypropoxy content	%	9.6	8.5 - 10.5	JP/USP/EP
Particle size: 20% cumulation (D20)	μm	36.9	20 - 40	Shin-Etsu
Particle size: Average (D50)	μm	70.0	50 - 80	Shin-Etsu
Particle size: 80% cumulation (D80)	μm	128.4	100 - 160	Shin-Etsu