

Product Specifications

HPMCP meets all the requirements for the Hypromellose Phthalate NF, Hypromellose Phthalate EP and Hypromellose Phthalate JP. Moreover, in addition to the tests prescribed in the aforementioned Pharmacopeias, Shin-Etsu carries out tests for methoxy content, hydroxypropoxy content, microbiological contamination, etc., in order to ensure strict quality control (self-GMP). Product specifications are shown in the following table.

Table 3 Specifications of HPMCP

Item/Grade	HP - 55	HP - 55S	HP - 50	
Nominal phthalyl content	31 %		24 %	Method
Labeled viscosity (cSt)	40 cSt	170 cSt	55 cSt	
Identification (IR)	Conforms			USP/NF
Viscosity* (cSt)	32 - 48 cSt	136 - 204 cSt	44 - 66 cSt	USP/NF
Water	Not more than 5.0 %			USP/NF
Residue on ignition	Not more than 0.20 %			USP/NF
Chloride	Not more than 0.07 %			USP/NF
Heavy metals	Not more than 0.001 %			USP/NF
Free phthalic acid	Not more than 1.0 %			USP/NF
Phthalyl content	27.0 - 35.0 %		21.0 - 27.0 %	USP/NF
Methoxy content**	18.0 - 22.0 %		20.0 - 24.0 %	USP/NF
Hydroxy propoxy content**	5.0 - 9.0 %		6.0 - 10.0 %	USP/NF
OVI	Conforms			USP/NF

* The viscosity unit in the EP is mPa·s, which is practically equivalent to cSt in the USP.

** in-house specification.