

Products Specifications

PHARMACOAT® meets all the requirement for the USP Hypromellose (Substitution type: 2910), EP Hypromellose and JP Hypromellose. Moreover, in addition to the tests prescribed in the aforementioned Pharmacopeias, Shin-Etsu carries out tests for foreign matter contamination, microbiological contamination, yellowness index, etc., in order to ensure strict quality control. PHARMACOAT® in

manufactured in accordance with the good manufacturing practice (self-GMP). A certificate of analysis commonly incorporating test results on the USP, are routinely attached to PHARMACOAT® products. Quality specifications are shown in the following table.

Table 7: Specifications of PHARMACOAT®

Grade	603	645	606	615	Method
Substitution type	2910				
Appearance	White to slightly off-white powder				Visual
Characters	Conforms				EP
Identification A~E	Conforms				USP
Appearance of solution	Conforms				EP
Viscosity	2.4~3.6 mPa·s	3.6~5.1 mPa·s	4.8~7.2 mPa·s	12.0~18.0 mPa·s	USP
pH	5.0~8.0				USP
Heavy metals	Not more than 20 ppm				USP
Loss on drying	5.0 % Max.				USP
Residue on ignition	1.5 % Max.				USP
Methoxy content	28.0~30.0 %				USP
Hydroxypropoxy content	7.0~12.0 %				USP

SB-4(Hypromellose 2208) is especially useful as a binder for sugar coating, which is an alternative source of gelatin and gum Arabic in sugar coating syrup. Please contact us for further information. Specification of SB-4 is available on request.

NOTE :

All the information and data in this brochure are accurate and reliable to the best of our knowledge, but they are intended only to provide recommendations or suggestions without guarantee or warranty. All of our products are sold on the understanding that buyers themselves will test our products to determine their suitability for particular applications. Buyers should also ensure that use of any product according to these data, recommendations, or suggestions does not infringe any patent, as Shin-Etsu will not accept liability for such infringement. Any warranty of merchantability or fitness for a particular purpose is hereby disclaimed.