

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

NAME: HYPROMELLOSE PHTHALATE

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Packaging and storage	+	+	+
Viscosity*	+	+	+
Water	+	+	+
Residue on ignition	+	+	+
Chloride	+	+	+
Limit of free phthalic acid	+	+	+
Phthalyl content	+	+	+

*The test for viscosity will be placed in the Functionality-related Characteristics section of EP

Legend

+ will adopt and implement; – will not stipulate

Non-harmonized attributes

Characters, Labeling, Heavy metals, Identification (IR)


Reagents and reference materials

Each pharmacopeia will adapt the text to take account of local reference materials and reagent specifications.


Date: 6 June 2006

Signatures:


European Pharmacopoeia


Agnès ARTIGES

Japanese Pharmacopoeia


for Akira Kawahara

United States Pharmacopeia


Todd L Cecil