

PHARMACOPOEIAL DISCUSSION GROUP
REVISION OF SIGN-OFF COVER SHEET
E-09 CROSCARMELLOSE SODIUM

(Revision of the sign-off cover sheet signed on 24 October 2001)

Item to be revised: see below

Harmonised attributes

	EP	JP	USP
Definition	+	+	+
Packaging and storage	+	+	+
Identification			
A	+	+	+
B	+	+	+
C (flame test)	- (1)	+	+
pH	+	+	+
Loss on drying	+	+	+
Residue on ignition	+	+	+
Degree of substitution	+	+	+
Settling volume	+	+	+

(1) EP includes a different test for the identification of sodium

Legend

+ will adopt and implement; - will not stipulate

Non-harmonized attributes

~~Characters/Description, Identification of sodium, Microbial limits, Heavy metals, Sodium chloride and sodium glycolate, Water-soluble substances, Organic volatile impurities, Packaging and storage/Containers and storage~~

Local requirements

EP	JP	USP
<u>Identification of sodium using potassium pyroantimonate</u>	<u>Heavy metals</u>	=

Reagents and reference materials

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

Date: May 26th 2016

Signatures:

European Pharmacopoeia
Pharmacopoeia



Japanese Pharmacopoeia



on behalf of H. Yamada

United States

