

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	+	+	+
Paekaging and storage	+	+	+
Identification			
A	+	+	+
B	+	+	+
C <u>(flame test)</u>	– <u>(1)</u>	+	+
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

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

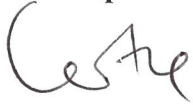
Reagents and reference materials

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

Date: 26-MAY-2016

Signatures:

European Pharmacopoeia
Pharmacopeia



Japanese Pharmacopoeia

K. Itanaka
on behalf of M. Yamada

United States

