

**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	+	+	+
<del>Packaging and storage</del>	<del>+</del>	<del>+</del>	<del>+</del>
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
Identification of sodium using potassium pyroantimonate	Heavy metals	=

**Reagents and reference materials**

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

Date: May 26<sup>th</sup> 2016

Signatures:

European Pharmacopoeia  
Pharmacopoeia



Japanese Pharmacopoeia



on behalf of H. Yamada

United States

