

**PHARMACOPOEIAL DISCUSSION GROUP**

**REVISION OF SIGN-OFF COVER SHEET  
E-10 CELLULOSE, MICROCRYSTALLINE**

(Revision of the sign-off cover sheet Rev. 1 signed on 11 May 2005)

**Item to be revised:** non-harmonised attributes, local requirements (EP, USP and JP).

**- Harmonised Attributes**

Attribute	EP	JP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
Conductivity	+	+	+
pH	+	+	+
Loss on drying	+	+ (1)	+ (1)
Residue on ignition	+	+	+
Bulk density	-	+	+ (2)
Water-soluble substances	+	+	+
Ether-soluble substances	+	+	+

(1) JP and USP will retain, as local requirement, that the value can be within a percentage range, as specified within the labelling

(2) USP will retain, as local requirement, that the Bulk density value is within the labelled specification.

**Legend**

+: will adopt and implement

-: will not stipulate

**- Non-harmonised attributes**

Characters/Description, ~~Heavy metals~~, ~~Microbial limits~~, Labelling, Containers and storage/Packaging and storage

**- Local requirements**

EP	JP	USP
<u>Solubility</u>	<u>Definition (reference to labelling)</u> , <u>Identification (2)G – dispersion test</u> , <u>Heavy metals, Sulfated ash (on 2.0 g)</u> .	<del>Organic volatile impurities</del> <u>Particle-size distribution estimation by analytical sieving</u>

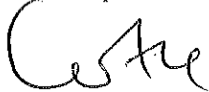
**Reagents and reference materials**

Each pharmacopoeia 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

*A. Honda*  
*on behalf of H. Yamada*

United States

