

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> , Identification (2)€ – dispersion test, <u>Heavy metals</u> , <u>Sulfated ash (on 2.0 g)</u> .	Organic volatile impurities Particle-size distribution estimation by analytical sieving

Reagents and reference materials

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

Date:

26 MAY - 2014

Signatures:

European Pharmacopoeia
Pharmacopoeia



Japanese Pharmacopoeia

W. Itokada
on behalf of M. Yamada

United States

