

PHARMACOPOEIAL DISCUSSION GROUP

REVISION OF SIGN-OFF COVER SHEET E-11 CELLULOSE, POWDERED

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

Item to be revised: non-harmonised attributes, local requirement (EP, JP, USP)

Harmonised Attributes

Attribute	EP	JP	USP
Definition	+	+	+
<u>Labelling</u>	-	+	+
Identification			
A	+	+	+
B	+	+	+
pH	+	+	+
Loss on drying	+	+	+
Residue on ignition	+	+	+
Water-soluble substances	+	+	+
Ether-soluble substances	+	+	+

Legend

+: will adopt and implement

-: will not stipulate

Non-harmonised attributes

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

Local requirements

EP	JP	USP
<u>Solubility</u>	<u>Definition (after partial hydrolysis as occasion demands)</u> , Identification (2)€ – dispersion test, <u>Heavy metals</u>	<u>Organic volatile impurities</u>

Reagents and reference materials


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

Date:

26-MAY-2012

Signatures:

European Pharmacopoeia
Pharmacopoeia



Japanese Pharmacopoeia

W. Yamaoka
on behalf of
H. Yamada

United States

