

## 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               | +  | +  | +   |
| Labelling                | -  | +  | -   |
| 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                         |
|------------|--|-----------------------------|
| Solubility | Definition (after partial hydrolysis as occasion demands). Identification (2)E – dispersion test, Heavy metals | Organic volatile impurities |

#### 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  
Pharmacopeia

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