

# PHARMACOPEIAL DISCUSSION GROUP

## SIGN-OFF DOCUMENT

### NAME: MAGNESIUM STEARATE

|                                | Harmonized attributes |    |     |
|--------------------------------|-----------------------|----|-----|
|                                | EP                    | JP | USP |
| Definition                     | +                     | +  | +   |
| Packaging and storage          | +                     | +  | +   |
| Identification                 |                       |    |     |
| A                              | +                     | +  | +   |
| B                              | +                     | +  | +   |
| Acidity or alkalinity          | +                     | +  | +   |
| Loss on drying                 | +                     | +  | +   |
| Limit of chloride              | +                     | +  | +   |
| Limit of sulfate               | +                     | +  | +   |
| Limit of cadmium               | +                     | -  | +   |
| Limit of nickel                | +                     | -  | +   |
| Limit of lead                  | +                     | -  | +   |
| Stearic acid and palmitic acid | +                     | +  | +   |
| Assay                          | +                     | +  | +   |

#### Legend

+ will adopt and implement; - will not stipulate

#### Non-harmonized attributes

Characters, Labeling, Microbial limits, Specific surface area


#### Local requirements


#### Reagents and reference materials


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

Date: 03 June, 2008

Signatures:

  
European Pharmacopoeia  
L. S. I. T. E. L.

  
Japanese Pharmacopoeia

  
United States Pharmacopoeia

for Toshio Nakagaki D. ARNE R. F. BERNEZ