

**PHARMCOPeIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET
CODE: E-22**

NAME: HYPROMELLOSE PHTHALATE

(Correction of the sign-off cover sheet of Corr. 1 signed on November 15, 2021)

Harmonised attributes

| Attribute | EP | JP | USP |
|-----------------------------|----|----|-----|
| Definition | + | + | + |
| Packaging and storage | + | + | + |
| Viscosity | + | + | + |
| Water | + | + | + |
| Residue on Ignition | + | + | + |
| Chloride | + | + | + |
| Limit of free phthalic acid | + | + | + |
| Phthalyl content | + | + | + |

Legend

+ will adopt and implement; - will not stipulate

Non-harmonised attributes

Characters, Labeling, Identification (IR)

Local requirements

| EP | JP | USP |
|--|---|------|
| Functionality-Related Characteristics (Viscosity*, Solubility, Phthalyl groups*) | Phthalic Acid, <i>System Suitability</i> – System performance | None |

* Viscosity and Phthalyl content/groups are harmonized attributes. They are also included in the Functionality-related Characteristics section of the EP monograph.

Reagents and reference materials

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

Each pharmacopeia will consider actual titrant concentration in equations according to their local rules of calculation for titration.

E-22

Correction sign-off cover sheet

December 2022

European Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Petra Doerr
82DD39EBFD74446...

Petra Doerr

20.12.2022

Japanese Pharmacopoeia

Signature

Name

Date

Y. Goda
for Y. Yoshida

Yukihiko Goda

20 Jan, 2023

United States Pharmacopoeia

Signature

Name

Date

DocuSigned by:
Kevin Moore
A7467E52FCC94E9...

Kevin Moore

12/15/2022