

PHARMCOPICIAL DISCUSSION GROUP
CORRECTION OF SIGN-OFF COVER SHEET

CODE: E-28

NAME: PETROLATUM

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

Harmonized attributes

Attribute	EP	JP	USP
Definition	+(1)	+(2)	+
Identification A (IR)	+	+	+
Identification B (Color)	+	+	+
Identification C (Drop Point)	+	-(3)	+
Consistency ⁽⁴⁾	+	+	+
Acidity or alkalinity	+	+	+
Residue on Ignition	+	+	+
Polycyclic aromatic hydrocarbons	+	+	+

(1) EP includes that "Yellow soft paraffin described in this monograph is not suitable for oral use."

(2) JP includes that "It may contain dibutylhydroxytoluene or appropriate type of tocopherol as a suitable antioxidant."

(3) JP implements "Melting Point" test instead of "Drop Point" test.

(4) JP lists this test in Functionality-Related Characteristics section of General Information, EP lists it in the Functionality-Related Characteristics section of the monograph and USP includes it in the monograph with a note that "In cases where there are no functionality-related concerns regarding the consistency of this article, this test may be omitted."

Legend

+ will adopt and implement; - will not stipulate

Non-harmonized attributes

Characters, Packaging and storage, Labeling

Local requirements

EP	JP	USP
Second Identification: Drop point, Iodine test, Appearance (Color)	Melting Point	None

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.

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

Yukihiro Goda

20 Jan, 2023

United States Pharmacopeia

Signature

Name

Date

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12/15/2022