

PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT Q-07 COLOUR (instrumental method)

Revision 1

It is understood that sign-off covers the technical content of the draft and each party will adapt it as necessary to conform to the usual presentation of the pharmacopoeia in question; such adaptation includes stipulation of the particular pharmacopoeia's reference materials and general chapters.

Harmonised provisions:

Provision	EP (1)	JP	USP
Principle	+	+	+
Spectrophotometric method	+	+	+
Determination of coloration	+	+	+

Legend

+: will adopt and implement

-: will not stipulate

(1) In EP this text will be part of chapter 2.2.2 which will cover the visual and the instrumental methods.

Non-harmonised provisions:

N/A

Local requirement

EP will include a sentence at the beginning of chapter 2.2.2: "Report the result with the method used (method I, method II or method III)".

JP will include the italicised sentence: "The relationship between the distribution coefficients and the tristimulus values (X, Y and Z) is given by the following equations, expressed in terms of integrals. *According to the definition in JIS Z 8120: 2001, the lower limit of the wavelength of visible radiation is generally taken between 360 nm and 400 nm and the upper limit between 760 nm and 830 nm.*"

European Pharmacopoeia

Signature

Name

LESTER

Date

27/11/19

Japanese Pharmacopoeia

Signature



Name

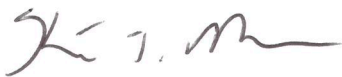
Haruhiko Okuda
for Fumi Yamamoto

Date

June 17, 2019

United States Pharmacopeia

Signature



Name

KEVIN MOORE

Date

24 JUN 2019