PHARMACOPOEIAL DISCUSSION GROUP SIGN-OFF DOCUMENT

CORRECTION 1

G-03 CONDUCTIVITY

(correction of the sign-off document signed on 13 September 2017)

Items to be corrected:

TEMPERATURE COMPENSATION: "In cases of very low conductivity (<10 µS/cm), such as purified pharmaceutical waters water for cleaning/rinsing purposes, two compensations need to be made."

CONDUCTIVITY MEASUREMENT OF FLUIDS: "For off-line <u>or at-line</u> batch measurements, ..."; "For continuous on-line or <u>at-line</u> measurements, ..."

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	JP	USP
Introduction	+	+	+
Apparatus	+	+	+
Cell Constant Determination	+	+	+
Calibration of Temperature	+	+	+
Calibration of Measurement	· · · ·	+	+
Electronics			
Temperature Compensation	+	+ (1)	+
Conductivity Measurement of Fluids	+	+ (2)	+

(1) "(e.g. purified water, water for injection)" not included in the JP.

(2) "at-line" not included in JP

Non-harmonised provisions:

-

Local requirement

EP	JP	USP
	The following sentences, "Non-linear temperature compensation data for a variety of solutions is widely available e.g., as described in ISO 7888 Water Quality- Determination of electrical conductivity.", is replaced to "Non-linear temperature compensation will carry out	In the Introduction, the second sentence reads "This chapter is intended for *other* fluid applications when conductivity"

temperature compensation using preprogrammed data in the instrument. Non-linear temperature compensation data for a variety of solutions is widely available, e.g. for natural waters, and for ultrapure water with traces of ammonia."	
	The following statement is added to the last sentence of the first paragraph in the introduction: "This chapter does not replace the official <u>Water Conductivity (645)</u> procedure, which is used to ensure the ionic purity of compendial waters such as <u>Water for Injection, Purified</u> <u>Water, Pure Steam</u> condensate, and <u>Sterile</u> <u>Water for Injection</u> , among others."
	The following NOTE is added at the end of the second paragraph of the Introduction: "[NOTE—For additional background information, see <u>Theory and</u> <u>Practice of Electrical</u> <u>Conductivity Measurements</u> <u>of Solutions (1644)</u> .]"

European Pharmacopoeia

Signature

(othe

Name

LEFITEL

UNOINS

Date

Japanese Pharmacopoeia

Signature

A Hunda

United States Pharmacopeia

Signature

Jur. M

Name Harnhiro Okuda for Fumi Yamamoto

Date oct 2nd, 2019

Date 02-05-2015

Name