PHARMACOPEIAL DISCUSSION GROUP

CORRECTION 1

E24-LACTOSE, MONOHYDRATE

(Correction to Rev. 2 signed on June 5, 2008)

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Clarity and color of solution	+(1)	+	+
Identification IR	+	+	+
Identification (TLC)	+(2)	-	+
Specific optical rotation	+	+	+
Acidity or alkalinity	+	+	+
Water	+	+	+
Residue on ignition	+	+	+
Loss on drying	-	+	+
Protein and light-absorbing impurities	+	+	+
Microbial limits (TAMC, *E. coli*)	+	+	+
Microbial limits (TYMC)	–	+	+

(1) In EP, reference suspension I is used to evaluate the opalescence of the solution in the test for clarity and colour of solution. Each pharmacopeia has similar but minor difference in the acceptance criteria.

(2) In EP, the identification test by TLC is included in the second series of identification.

Legend + will adopt and implement; – will not stipulate

Non-harmonized attributes

Characters/Description, Packaging and storage, Labeling

Local requirements

EP	JP	USP
Identification (water), Second identification (TLC, colour reaction, water); FRC (Particle-size distribution, Bulk and tapped density)	The definition section also covers granulated lactose, It also states: "It is a disaccharide obtained from milk, consist of one unit of glucose and one unit of galactose." The test for water is restricted to granulated forms (4.0-5.5%);	The definition section includes the following: "NOTE—Lactose Monohydrate may be modified as to its physical characteristics. It may contain varying proportions of amorphous lactose."

	Heavy metals; Microbial limits: *Salmonella*	

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

European Pharmacopoeia

Signature: Date

2/10/19

Japanese Pharmacopoeia

Signature: Date

Oct 2nd. 2019

United States Pharmacopeia

Signature: Date

02-Oct-2019