PHARMACOPEIAL DISCUSSION GROUP

CORRECTION 1

E23: LACTOSE, ANHYDROUS

Correction to Rev. 4 signed on 26 October 2016

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Identification (IR)	+	+	+
Identification (TLC)	+(1)	-	+
Clarity and colour of solution	+	+(2)	+
Specific optical rotation	+	+	+
Acidity or alkalinity	+	+	+
Loss on drying	+(3)	+	+
Water	+	+	+
Content of alpha and beta anomers	+(4)	+	–
Residue on ignition	+	+	+
Protein and light-absorbing impurities	+	+	+
Microbial limits (TAMC, E.coli)	+	+	+
Microbial limits (TYMC)	–	+	+

(1) In EP, the identification by TLC is included in the second series of identification.
(2) In JP, reference suspension I is not 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.
(3) & (4) In EP, "Contents of alpha and beta anomers" and "Loss on drying" are included in the non-mandatory FRC section. EP will not stipulate the specification for Loss on drying.

Legend: + will adopt and implement; – will not stipulate

Non-harmonised attributes
Characters/Description, Labeling, Packaging and storage

Local requirements

EP	JP	USP
Identification (water), Second identification (TLC, colour	Microbial limits: *Salmonella*; Heavy metals; Content of	Content of alpha and beta anomers (USP requires a limit

reaction, water); FRC (particle-size distribution, Bulk and tapped density, Alpha- and beta-lactose, Loss on drying)	alpha and beta anomers (System Repeatability)	to be stated on the label, where needed)

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