

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: <i>Salmonella</i> ; 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)
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Reagents and reference materials

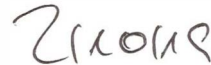
Each pharmacopeia will adapt the text to take account of local reference materials and reagent specifications.

European Pharmacopoeia

Signature:



Date

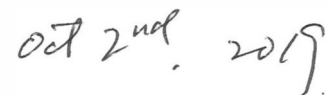


Japanese Pharmacopoeia

Signature:



Date



United States Pharmacopoeia

Signature:



Date

