

# PHARMACOPEIAL DISCUSSION GROUP

## SIGN-OFF DOCUMENT

### E23: LACTOSE, ANHYDROUS

Revision of sign-off cover sheet Rev. 4 signed on 9 November 2010

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

In EP, the tests "content of alpha and beta anomers" and "loss on drying" will be in the non-mandatory FRC section. EP will not stipulate the specification for loss on drying.

In JP, reference suspension I will not be used to evaluate the opalescence of the solution in the test for clarity and colour of solution.

**Legend:** + will adopt and implement; - will not stipulate

#### Non-harmonised attributes

Characters/Description, Labeling, ~~Heavy metals~~, Packaging and storage

#### Local requirements

Identification B and C (USP), Identification D (water) (EP), Microbial contamination TYMC (USP), Microbial contamination TYMC -Salmonella (JP), ~~Particle size distribution (USP)~~, Particle-size distribution (EP - FRC), Bulk and tapped density (EP - FRC), Content of alpha and beta anomers (USP will require a limit to be stated on the label, where needed), ~~Heavy metals (JP)~~

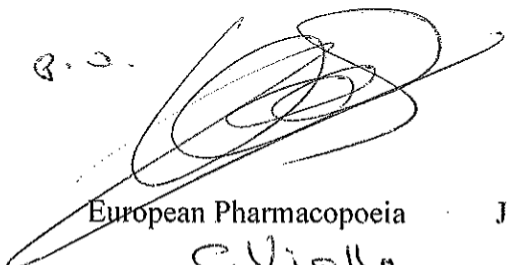
#### Reagents and reference materials


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

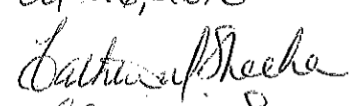
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Date: 26 Oct 2016

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