

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT (REVISION 1)

NAME: LACTOSE MONOHYDRATE

	Harmonized attributes		
	EP	JP	USP
Definition ^{1,2}	+	+	+
Clarity and color of solution	+	+	+
Identification			
A	+	+	+
Specific rotation	+	+	+
Acidity or alkalinity	+	+	+
Water ¹	+	+	+
Residue on ignition	+	+	+
Protein and light-absorbing impurities	+	+	+

¹The definition section of JP also covers granulated lactose, with a lower limit of 4.0 percent of water.

²The definition section of USP includes the following: "NOTE—Lactose Monohydrate may be modified as to its physical characteristics. It may contain varying proportions of amorphous lactose."

Legend

+ will adopt and implement; – will not stipulate

Non-harmonized attributes

Characters, Microbial limits, Heavy metals, Packaging and storage, Labeling

Local requirements

Identification B and C (USP), Particle size distribution (USP), Loss on drying (USP).

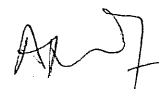
Reagents and reference materials

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

Date: Oct 25, 2006

Signatures:

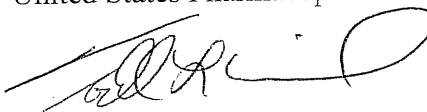
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