

**PHARMACOPOEIAL DISCUSSION GROUP  
SIGN-OFF DOCUMENT**

**E24-LACTOSE, MONOHYDRATE (REV.2 -EXPEDITED)**

Attribute	EP	JP	USP
Definition <sup>1,2</sup>	+	+	+
Clarity and Color of solution	+	+	+
Identification A	+	+	+
Specific rotation	+	+	+
Acidity or alkalinity	+	+	+
Water <sup>1</sup>	+	+	+
Residue on ignition	+	+	+
Protein and light-absorbing impurities	+	+	+

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

<sup>1</sup> The definition of JP also covers granulated lactose, with a lower limit of 4.0 percent of water

<sup>2</sup> The 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."

**Non-harmonised 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).

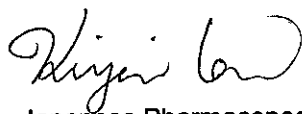
**Reagents and reference materials**

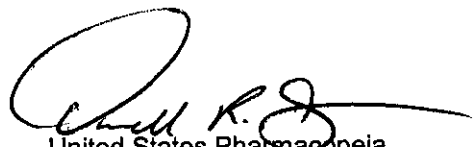
Each pharmacopoeia will adapt the text to take account of local reference substances and spectra and reagent specifications.

Date: 05/06/08

Signatures:

  
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