

**PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT**

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

Attribute	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	+	+	+

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

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

² 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).

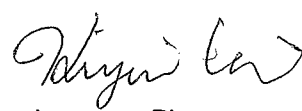
Reagents and reference materials

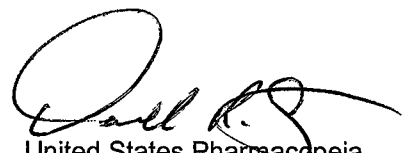
Each pharmacopoeia will adapt the text to take account of local reference substances and spectra and reagent specifications.

Date: 07/06/07

Signatures:


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