

02-10-16

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

NAME: LACTOSE MONOHYDRATE

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

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

Legend

+ will adopt and implement; - will not stipulate

Non-harmonized attributes

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

Local requirements

Identification Band C (USP), Particle size distribution (USP).

Reagents and reference materials

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

Date: 10 sept 2002

Signatures:

European Pharmacopoeia

AWJ
A-ARTIGES

Japanese Pharmacopoeia

Osashi' Valced -
for MICHIMARU ABE

United States Pharmacopeia

Emi B. Steiner for
Roger L. Williams