

02-10-17

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

NAME: ANHYDROUS LACTOSE

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Labeling	+	+	+
Clarity and color of solution	+	+	+
Identification			
A	+	+	+
Specific rotation	+	+	+
Acidity or alkalinity	+	+	+
Water	+	+	+
Content of alpha and beta anomers	+	+	+
Residue on ignition	+	+	+
Protein and light-absorbing impurities	+	+	+
Loss on Drying	-	+	+

Legend

+ will adopt and implement; - will not stipulate

Non-harmonized attributes

Characters, Microbial limits, Heavy metals, Packaging and storage

Local requirements

Identification B and C (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:

A. ARTIGES
European Pharmacopoeia

Artiges

Japanese Pharmacopoeia

Chagushi Takahashi
for MICHIMARU ABE

United States Pharmacopeia

Ein B. Schmitt for
Roger L. Williams