

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT (REVISION 1)

NAME: ANHYDROUS LACTOSE

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

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:

Signatures:

5-February-2003

European Pharmacopoeia

Japanese Pharmacopoeia

United States Pharmacopoeia

AMJ
A. ARTIGES

M. ABE
M. ABE

Ein Blain