

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT (REVISION 2)

NAME: ANHYDROUS LACTOSE

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Clarity and color of solution	+	+	+
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, Labeling, Microbial limits, Heavy metals, Packaging and storage, Identification(IR)

Local requirements

Identification B and C (USP), Particle size distribution (USP), Particle size distribution EP (FRC)

Reagents and reference materials

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

Date: 8 November - 2005

Signatures:

AMJ
 Agnes ARTIGES
 European Pharmacopoeia

Heremichi Ogasawara
 for AKIRA KAWAHARA
 Japanese Pharmacopoeia

Eric B. Sherman
 Eric B. Sherman
 United States Pharmacopeia