

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 - 2006

Signatures:


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