PHARMACOPEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT

E23: LACTOSE, ANHYDROUS (Rev. 4)

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Identification (IR)	+	+	+
Clarity and colour 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	+	+	+
Microbial contamination	+	+	+

In EP, the tests "content of alpha and beta anomers" and "loss on drying" will be in the non-mandatory FRC section. EP will not stipulate the specification for loss on drying.
In JP, reference suspension I will not be used to evaluate the opalescence of the solution in the test for clarity and colour of solution.

Legend: + will adopt and implement; – will not stipulate

Non-harmonised attributes
Characters, Labeling, Heavy metals, Packaging and storage

Local requirements
Identification B and C (USP), Microbial contamination TYMC (USP), Microbial contamination TYMC-Salmonella (JP), Particle size distribution (USP), Particle-size distribution (EP – FRC), Bulk and tapped density (EP – FRC), Content of alpha and beta anomers (USP will require a limit to be stated on the label, where needed)

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

Date: 9/11/10

Signatures:

European Pharmacopoeia

for Masatoshi Narita
Japanese Pharmacopoeia

United States Pharmacopeia