

**PHARMACOPOEIAL DISCUSSION GROUP  
SIGN-OFF DOCUMENT**

**E23-LACTOSE, ANHYDROUS (REV.3 -EXPEDITED)**

| Attribute                              | 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-harmonised 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 pharmacopoeia will adapt the text to take account of local reference substances and spectra and reagent specifications.

Date: 0706108

Signatures:

  
European Pharmacopoeia  
LESTER

  
Japanese Pharmacopoeia  
for Toshiko Nakagaki

  
United States Pharmacopoeia  
DARRELL R. ABERNETHY