

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

E23: LACTOSE, ANHYDROUS

Revision of sign-off cover sheet Rev. 4 signed on 9 November 2010

| | 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 limits (TAMC, E.coli) | + | + | + |

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/Description, Labeling, ~~Heavy metals~~, Packaging and storage

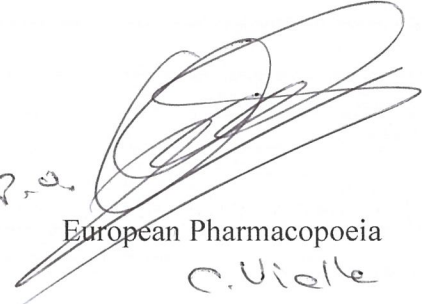
Local requirements


Identification B ~~and C~~ (USP), Identification D (water) (EP), 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), Heavy metals (JP)

Reagents and reference materials

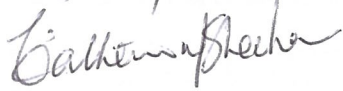
Each pharmacopeia will adapt the text to take account of local reference materials and reagent specifications.

Date: 26 Oct 2016


European Pharmacopoeia
C. Vielle

Oct 26 2016

Hanshiro Aenda
for Masamichi Yamada
Japanese Pharmacopoeia

Signatures:

Oct 26, 2016

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