

Specification
Lactose Pharma Grade, Eur. Ph. – USP/NF – JP

Definition

O-β-D-Galactopyranosyl-(1- → 4)-α-D-glucopyranose monohydrate

Description

Appearance	white, crystalline powder
Solubility	soluble in water

Identification and Analysis

Identification A, B, C, D	acc. Eur. Ph.
Appearance of solution	clear, comparable to reference
Acidity and Alkalinity	< 0,4 ml
Spec. optical rotation	54,4 – 55,9
Absorption: 400nm	max. 0,04
210 – 220nm	max. 0,25
270 – 300nm	max. 0,07
Heavy metals	max. 5 ppm
Water	4,5 – 5,5 %
Sulfated ash	max. 0,1%
Particle size distribution	accordant
Bulk – and tapped density	accordant

Microbiological Data

Total Plate Count	max. 100/g
E. Coli	neg./g

Packaging and Storage

Paper bag, multilayer, with PE-Inliner, 25 kg; 750 kg per pallet
Big bag, PP, 1000 kg
In closed package, dry, clean and protected from light and off
flavours (rel. humidity max.65 %)

Shelf Life

36 months (25 kg bag) after date of production
36 months (1000 kg big bag) after date of production