

Technical Data Sheet

Report No: 22116

Product Name	Lactose Monohydrate 200mesh
Manufacturer	Jiang Su Dawning Pharmaceutical Co., Ltd.
Basis for Analysis	Ph. Eur. 10.0
Tests	Specifications
Characters	Appearance: White or almost white, crystalline powder Solubility: freely soluble in water, practically insoluble in ethanol (96 per cent)
Identification	A、 Infrared absorption spectrophotometry D、 Water.
Appearance of solution	Should be complied
Acidity or alkalinity	NMT 0.4mL of 0.1 M sodium hydroxide
Specific optical rotation	+54.4°~ +55.9°
Absorbance: proteins and light-absorbing impurities	— at 400 nm: maximum 0.04; — from 210 nm to 220 nm: maximum 0.25; — from 270 nm to 300 nm: maximum 0.07.
Water	4.5%~5.5%
Sulfated ash	NMT 0.1%
Microbial contamination	TAMC: acceptance criterion 10 ² CFU/g Absence of Escherichia coli
The results above meet all requirements under LACTOSE, MONOHYDRATE in Ph. Eur. 10.0.	
Reported by:	Approved by: