

## Technical Data Sheet

Report No: 22117

<b>Product Name</b>	Lactose Monohydrate 80 mesh
<b>Manufacturer</b>	Jiang Su Dawning Pharmaceutical Co., Ltd.
<b>Basis for Analysis</b>	<b>Ph. Eur. 10.0</b>
<b>Tests</b>	<b>Specifications</b>
<b>Characters</b>	Appearance: White or almost white, crystalline powder Solubility: freely soluble in water, practically insoluble in ethanol (96 per cent)
<b>Identification</b>	A. Infrared absorption spectrophotometry D. Water.
<b>Appearance of solution</b>	Should be complied
<b>Acidity or alkalinity</b>	NMT 0.4mL of 0.1 M sodium hydroxide
<b>Specific optical rotation</b>	+54.4°~ +55.9°
<b>Absorbance: proteins and light-absorbing impurities</b>	— at 400 nm: maximum 0.04; — from 210 nm to 220 nm: maximum 0.25; — from 270 nm to 300 nm: maximum 0.07.
<b>Water</b>	4.5%~5.5%
<b>Sulfated ash</b>	NMT 0.1%
<b>Microbial contamination</b>	TAMC: acceptance criterion 10 <sup>2</sup> CFU/g Absence of Escherichia coli
<b>The results above meet all requirements under LACTOSE, MONOHYDRATE in Ph. Eur. 10.0.</b>	
<b>Reported by:</b>	<b>Approved by:</b>