

**Lactose Monohydrate, Pharma**

C <sub>12</sub> H <sub>22</sub> O <sub>11</sub> ·H <sub>2</sub> O	FW. 360.32	Melting Point	202 °C
CAS-No.	10039-26-6		
Code	BP1449		

**Specifications**

( Meets Ph.Eur, BP, USP/NF )

Appearance	White or almost white, crystalline powder
Identity	Passes test
Appearance of solution	Clear and not more intensely coloured than reference solution BY <sub>7</sub>
Solubility	Passes test
Clarity and color of solution	Passes test
Acidity or Alkalinity	Passes test
Specific optical rotation	+ 54.4 to +55.9
Absorbance (Proteins and UV-absorbing impurities)	Passes test
Heavy metals (as Pb)	5 ppm max.
Water	4.5 - 5.5%
Residue after Ignition	0.1% max.
Loss on drying	0.5% max.
Microbiological purity (Total aerobic microbial count, TAMC)	100 CFU/g max.
Microbiological purity (Total yeast and mould count, TYMC)	50 CFU/g max.
Escherichia coli (absent in 1 g)	Passes test
Salmonella ssp (absent 10 g)	Passes test

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