

Specification Sheet

Product Name: **L-Cysteine hydrochloride monohydrate**
 Specifications & Purity: PharmPure™, USP, JP, Ph.Eur., pharmaceutical grade, GMP
 SKU #: **L433361**

Parameter	Limit Values
Assay(alkalimetric , calculated on dried substance)	98.5-101 (%)
Appearance(L433361)	white or almost white, crystalline powder or colourless crystals
PH(10g/l,CO2-free water)	1.3- 2.3
Solubility:freely soluble in water, slightly soluble in ethanol (96 per cent)	Pass
Identity (IR-spectrum)	conforms
Identity(specific rotation)	Pass
Identity(TLC)	Passes test
Identify(EP)(D)	Pass
Identity(EP)(E)	conforms
Appearance of solution,clear and not more intense in color than reference solution BY6	Pass
Specific Rotation [a] ₂₀ /D(C=8 in hydrochloric acid R1,calc.on dried substance)	5.5-7 (°)
Specific Rotation [a] ₂₀ /D(C=8 in 6N HCl,calc. on dried substance)	6-7.5 (°)
Specific Rotation [a] ₂₅ /D(C=8 in 6N HCl , calc.on dried substance)	5.7-6.8 (°)
Related Compounds(Individual impurities)	0-0.5 (%)
Related Compounds(Total impurities)	0-2 (%)
Ninhydrin-positive substances(LC)(impurity A(570nm)	0-0.5 (%)
Ninhydrin-positive substances(LC)(any ninhydrin-positive impurity)	0-0.2 (%)
Ninhydrin-positive substances(LC)(ammonium(570nm)	0-0.02 (%)
Ninhydrin-positive substances(LC)(total impurities)	0-1 (%)
Sulfate(SO ₄)	0-210 (ppm)
Heavy metals	0-10 (ppm)
Fe(iron)	0-10 (ppm)
Residue on Ignition	0-0.1 (%)
Loss on drying (Vacuum< 2,0 kPa, P2O5,20 h)	8.5-12.0 (%)
Residual solvents (ICH (Q3C))excluded by manufacturing process	pass
Bacterial endotoxins	0-6 (IU/g OR u/g)
Microbiological test(total aerobic microbial count(TAMC))	0-100 (CFU/g)
Microbiological test(total yeast and mould count(TYMC))	0-100 (CFU/g)