

PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE

ITEMS	SPECIFICATIONS
APPEARANCE	White or off-white powder
SOLUBILITY	Freely soluble in water, soluble in methanol, insoluble in acetone
IDENTIFICATION a) IR b) UV c) Reaction on chlorides	Complies with the test in the analytical procedure Complies with the test in the analytical procedure Complies with the test in the analytical procedure
APPEARANCE OF SOLUTION	The sample solution should be clear
PH VALUE	1.2~1.8
SPECIFIC OPTICAL ROTATION	+10.0° ~ +14.0°
RELATED SUBSTANCES ➤ Known individual impurity ➤ Unknown individual impurity ➤ Total impurities	NMT 0.15% NMT 0.10% NMT 0.5%
ENANTIOMERIC PURITY	NLT 99.5%
HEAVY METALS	NMT 10 ppm
LOSS ON DRYING	NMT 0.5%
SULPHATED ASH	NMT 0.2%
CONTENT	98.0%~102.0% (calculated with the reference to the dry substance)
WATER CONTENT a) Acetic acid (HPLC) b) Acetone (GC)	NMT 800 ppm NMT 5000 ppm