

PRODUCT: LEVOCETIRIZINE HYDROCHLORIDE

ITEMS	SPECIFICATIONS
APPEARANCE	A white or almost white crystalline powder
SPECIFIC OPTICAL ROTATION	+10.5° ~ +15.0°
IDENTIFICATION a) IR b) Reaction of chloride	Should comply Should comply
RELATED SUBSTANCES ➤ Each single impurity ➤ Total impurities	≤0.10% ≤0.5%
CLARITY	Should comply
COLOUR OF SOLUTION	BY ₇
PH	1.2~1.8
LOSS ON DRYING	≤ 0.5%
SULPHATED ASH	≤0.2%
HEAVY METALS	≤10 ppm
RESIDUAL SOLVENTS a) Acetone b) Dichloromethane c) Toluene d) n-Hexane e) Mesityl oxide	≤3000 ppm ≤600ppm ≤890ppm ≤220ppm ≤1000ppm
MICROBIOLOGICAL LIMIT TESTS ➤ Bacteria ➤ Mold and Yeast ➤ E. Coli	≤1000 cfu/g ≤1000 cfu/g Absent in 10g of product
ASSAY	98.0%~99.0% (calculated on the dried basis)