

PRODUCT: IMIDAPRIL HYDROCHLORIDE

ITEMS	SPECIFICATIONS
DESCRIPTION	White to almost white powder
SOLUBILITY	Freely soluble in methanol, soluble in ethanol and water
IDENTIFICATION=> IR	The IR spectrum of the test sample should be similar to that of working standard
SPECIFIC OPTICAL ROTATION	-60.0° ~ -65.0°
WATER CONTENT BY KF	NMT 0.5 % w/w
RESIDUE ON IGNITION	NMT 0.1% w/w
CHLORIDE CONTENT	7.8% w/w ~ 8.4% w/w
RELATED SUBSTANCES BY HPLC	
➤ Imidapril impurity-A	NMT 0.1 % w/w
➤ Imidapril impurity-B	NMT 0.1 % w/w
➤ Imidapril impurity-C	NMT 0.1 % w/w
➤ Any other impurity	NMT 0.10 % w/w
➤ Total impurities	NMT 1.0 % w/w
ASSAY BY HPLC (on anhydrous basis)	99.0% w/w ~ 101.0% w/w
RESIDUAL SOLVENTS BY GC	
a) Methanol	NMT 3000 ppm
b) Acetone	NMT 5000 ppm
c) 1,4-Dioxane	NMT 380 ppm