



Certificate of Analysis

Product name : Enalapril Maleate
 Batch number : 5112-10-071
 Batch quantity : 300kgs
 Manufacturing date : AUG. 10, 2010
 Expiry date : JULY , 2014

TESTS	STANDARDS	RESULTS
Appearance	A white or almost white crystalline powder	Complies
Solubility	Freely soluble in methanol, sparingly soluble in water, practically insoluble in dichloromethane	Complies
Melting point	140°C~147°C	140.5-141.5°C
Identification	1) The infrared absorption spectrum is concordant with Enalapril Maleate RS. 2) The retention time of the major peak in the chromatogram of the Assay preparation corresponds to the standard preparation obtained as directed in the assay.	Complies Complies
Specific rotation	-41.0° ~-43.5°	-42.0°
Loss on drying	Not more than 1.0%	0.1%
Residue on ignition	Not more than 0.2%	0.1%
Heavy metals	Not more than 0.001%	< 0.001%
Related substances		
Impurity(RRT=1.10)	Not more than 1.0%	N.D.
Any other impurity	Not more than 0.3%	0.12%
Total impurities	Not more than 2.0%	0.24%
Assay(HPLC)	Not less than 98.0% and not more than 102.0%, calculated on the dried basis	99.2%
Residual solvent(GC)		
Ethanol	Not more than 0.5%	0.001%

Conclusion : The product meets the requirement of USP32