



Specialized in chemicals

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Certificate of Analysis

Product	Enalapril Maleate	Batch Number	TNJ20150320025
CAS No.	76095-16-4	Packing	25kg/drum
M F	C ₂₄ H ₃₂ N ₂ O ₉	MFG Date	Mar,20,2015
N.W.	25.00KGS	Analysis Date	Mar,25,2015
G.W.	26.50KGS	Retest Date	Mar,19,2017
Items	Specification	Testing Results	
Appearance	Off white crystalline powder	Conforms	
Identification	A: IR spectrum accordance with that of CRS	Conforms	
	B: Major peak in chromatogram obtain in the test solution in the assay accordance with that of reference solution	Conforms	
Specific Rotation		Between -41.0 ° and -43.5 °	-41.2 °
Related substances	RRT 1.1	≤1.0%	Not detected
	Other Individual impurity	≤0.3%	0.07%
	Total impurities	≤2.0%	0.13%
Loss on drying		≤1.0%	0.06%
Heavy metals		≤0.001%	<0.001%
Residue on ignition		≤0.2%	0.04%
Residual solvents	Ethanol	≤5000ppm	41ppm
	Acetone	≤5000ppm	Not detected
	Dichloromethane	≤600ppm	Not detected
	N-Hexane	≤290ppm	Not detected
Assay (anhydrous basis)		98.0%-102.0%	99.9%
Prepared by Dong Mei		Checked by Wang Tianyi	Approved by Liu Wu
Conclusion	The Quality of the above said is in conformity with USP 37 .		
Storage	Stored in dry and ventilation place, far from heat and water.		
COA Issuer	Quality Control Team-Technology Department		

