



NOSCH LABS PRIVATE LIMITED

(100% EXPORT ORIENTED UNIT)

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CERTIFICATE OF ANALYSIS

Product Name : ENALAPRIL MALEATE EP		Reference : EP	
Batch Number : EM0030911		Mfg. Date : Sept. 2011	
Quantity : 2.5 Kgs		Exp.Date. : Aug. 2016	
A.R.Number : 11EMC09003		Date of Analysis: 25.01.2012	
Whom to supply: Oceanic Pharmachem Pvt.Ltd.		Sampled by : G.Pavan	
Sl.No	TESTS	SPECIFICATIONS	RESULTS
1.0	Description	A white or almost white crystalline powder.	A white crystalline powder
2.0	Solubility	Freely soluble in Methanol, sparingly soluble in water, practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides.	Complies
3.0	Melting range	About 144°C	144.9° to 146.0°C
4.0	Identification by IR	The Infrared Absorption spectrum of sample is concordant with that of reference standard.	Complies
5.0	Appearance of solution	Dissolve 0.25 g in distilled water and dilute to 25.0 ml with the same solvent (Solution S). The resulting solution should be clear & colourless.	Complies
6.0	pH (Solution S)	Between 2.4 to 2.9.	2.63
7.0	Specific optical rotation (determined on solution S and calculated with reference to the dried substance)	Between -48.0° and -51.0°	-48.75°
8.0	Loss on drying (At 105°C for 3 hrs)	Not more than 1.0% w/w	0.15% w/w
9.0	Sulphated Ash	Not more than 0.1% w/w	0.06% w/w
10.0	Heavy metals	Not more than 10 ppm	Less than 10 ppm
11.0	Residual solvents	Methylene dichloride - Not more than 600 ppm Acetone - Not more than 5000 ppm Toluene - Not more than 890 ppm n-Hexane - Not more than 290 ppm	Not detected Not detected Not detected Not detected
12.0	Related substances by HPLC	Impurity A : Not more than 1.0% Impurity B : Not more than 0.3% Impurity C : Not more than 0.3% Impurity D : Not more than 0.3% Impurity E : Not more than 0.3% Impurity H : Not more than 0.3% Any other unspecified impurity: Not more than 0.10% Total impurities other than A: Not more than 1.0%	Nil 0.04% Nil Nil Nil 0.10% Nil 0.14%
13.0	Assay by Potentiometry (On dried basis)	Not less than 98.5% and not more than 101.5% w/w.	100.08% w/w
Note : The product conforms to the above specifications			
Analysed by : <i>M</i> Date: 25/01/12		Checked by: <i>ps</i> Date: 25/01/12	Approved by: <i>[Signature]</i> Date: 25.01.2012

WORKS : Unit II Survey No. 14, IDA, Gaddapotharam (V), Kazipally, Jinnaram (M), Medak (Dist.) 502 319, A.P., INDIA

Lot FMB

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