



VASUDHA PHARMA CHEM LTD

VASUDHA PHARMA CHEM LIMITED

78/A, VENGAL RAO NAGAR, HYDERABAD - 38, INDIA

PHONE: 91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576

E-MAIL: vasudha@vasudhapharma.com, Website: www.vasudhapharma.com

CERTIFICATE OF ANALYSIS

Name of the Product	:	AMITRIPTYLINE HYDROCHLORIDE EP			
Batch Number	:	CAMPT/1510045	Analyzed on	:	27/10/2015
Manufacturing Date	:	SEP 2015	Expiry Date	:	AUG 2020
Quantity	:	265.50 Kg	A.R.No	:	AMPT/15055

S.No	TEST	RESULT	SPECIFICATION
1.0	CHARACTERS		
1.1	Appearance	White powder	White or almost white powder or colourless crystals.
1.2	Solubility	Complies	Freely soluble in water, in ethanol (96 percent) and in methylene chloride.
2.0	IDENTIFICATION		
2.1	Infrared spectrum (KBr disc)	Complies	The IR spectrum of the sample should be concordant with that of Reference / working standard.
2.2	Chlorides test	Complies	The solution should give reaction (a) of chlorides.
3.0	TESTS		
3.1	Appearance of solution	Complies	The solution is clear and not more intensely coloured than reference solution B ₇ .
3.2	Acidity (or) Alkalinity	Complies	The solution should be yellow with alkali and red with acid.
3.3	Related substances by HPLC (%)		
	Impurity-A	BDL	Not more than 0.05
	Impurity-B	0.05	Not more than 0.10
	Single maximum unspecified impurity	0.05	Not more than 0.10
	Total impurities	0.10	Not more than 0.3

	Prepared By	Checked By	Approved By
Signature	<i>[Signature]</i> 25/11/15	<i>[Signature]</i> 25/11/15	<i>[Signature]</i> 25/11/15
Name	H. Siva Rama Krishna	P. V. Rama Ravi	V. Harsh Prabha
Designation	Chemist	Executive	Tr. Manager

Manufactured at:

M/s Vasudha Pharma Chem Ltd, Unit-III, Plot No:23&24, J.N.Pharma City, Parawada, Visakhapatnam 531 019.

CQA/002/F05/00

EFFECTIVE DATE: 01/10/2014

Page 1 of 2



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3.4	Heavy metals (ppm)	Less than 20	Not more than 20	
3.5	Loss on drying (%w/w)	0.13	Not more than 0.50	
3.6	Sulfated ash (%w/w)	0.05	Not more than 0.10	
3.7	Assay by HPLC on dried basis (%w/w)	100.0	Not less than 99.0 and Not more than 101.0	
4.0	ADDITIONAL TEST			
4.1	Residual solvents by GC with HSS (ppm)			
	1	Toluene	53	Not more than 500
	2	Tetrahydrofuran	BDL	Not more than 500
	3	Methanol	BDL	Not more than 500
	4	Acetone	BDL	Not more than 500

"BDL" indicates Below Detection Limit.

Remarks : The material complies as per the EP specification.

	Prepared By	Checked By	Approved By
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Name	V. Giridhar Reddy	P. V. Rama Raju	V. Hari Prasad
Designation	Chemist	Executive	Gr. Manager

Manufactured at:

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Page 2 of 2