 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 Ph.Eur.	
Batch Number	:	CAMPT/2004019	A.R.No. : AMPT/20046
Manufacturing Date	:	APR 2020	Expiry Date : MAR 2025
Batch Quantity	:	258.70 Kg	Analyzed on : 25/04/2020
S.No.	TEST	RESULT	SPECIFICATION
1.0	CHARACTERS		
1.1	Appearance	White crystalline 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	Below disregard limit	Not more than 0.1
	Single maximum unspecified impurity	Below disregard limit	Not more than 0.10
	Total impurities	Below disregard limit	Not more than 0.3

	PREPARED BY	CHECKED BY	APPROVED BY
Signature	<i>G. Veeranna</i>	<i>P.V. Rama Ram</i>	<i>Ch. Ravi Kumar</i>
Name	G. Veeranna	P.V. Rama Ram	Ch. Ravi Kumar
Designation	Executive (QC)	Jr. Manager (QC)	Asst. Manager (QC)


Manufactured at:

M/s Vasudha Pharma Chem Limited, Unit-III, Plot No:23&24, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), Visakhapatnam District- 531019, Andhra Pradesh, India. Ph: 08924-236227, 236228

CQA/002/F05/00

EFFECTIVE DATE: 01/10/2014

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S.No.	TEST	RESULT	SPECIFICATION
3.4	Loss on drying (%w/w)	0.31	Not more than 0.5
3.5	Sulfated ash (%w/w)	0.06	Not more than 0.1
3.6	Assay by HPLC on dried basis (%w/w)	99.9	Not less than 99.0 and Not more than 101.0
4.0	Additional tests		
4.1	Residual solvents (By GC with HSS ,ppm)		
	Methanol	BDL	Not more than 500
	Acetone	BQL	Not more than 500
	Tetrahydrofuran	BDL	Not more than 500
	Toluene	175	Not more than 500

“BDL” indicates Below Detection Limit.

“BQL” indicates Below Quantification Limit.

Remarks: The material complies as per the Ph.Eur Specification.

Transportation : Material transit in ambient condition.

Storage: Recommended to store the material at 25±2°C at your site (Excursions allowed between 15 to 30°C).

	PREPARED BY	CHECKED BY	APPROVED BY
Signature	<i>G. Veeranna</i>	<i>P. V. Ram</i>	<i>Ch. Ravi Kumar</i>
Name	G. Veeranna	P. V. Ram	Ch. Ravi Kumar
Designation	Executive (QC)	JV Manager (A.C)	Asst Manager (QC)

Manufactured at:

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