

Name of the product	:	AMITRIPTYLINE HYDROCHLORIDE Ph.Eur.	G240052
Batch Number	:	CAMPT/2402008	Analyzed on : 23/02/2024
Manufacturing Date	:	FEB 2024	Retest Date : JAN 2029
Quantity	:	255.0 Kg	AR No. : FP/24134

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 (BDL Limit :0.0083)	Not more than 0.05
	Impurity-B	0.03	Not more than 0.1
	Single maximum unspecified impurity	Not detected	Not more than 0.10
	Total impurities	0.03	Not more than 0.3

	Prepared By QC	Checked By QC	Approved By QC
Signature & date	M. P. 03/05/24	N. S. R. 03/05/24	G. T. 03/05/24
Name	P. Murali	N. S. R. J. N.	G. T. Murali
Designation	Executive	Jr. Manager	Sr. Manager

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

CQA/002/F05/01

EFFECTIVE DATE: 01/01/2021

G240052

QUALITY ASSURANCE RELEASE

Customer Name: Magis Pharma

VASUDHA PHARMA CHEM. LIMITED

VASUDHA PHARMA CHEM LIMITED 03.00 Kg

78/A, Vengalrao Nagar, Hyderabad-500 038,

Telangana State, India

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

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CERTIFICATE OF ANALYSIS

Name of the product	:	AMITRIPTYLINE HYDROCHLORIDE Ph.Eur.			
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S. No.	TEST		RESULT	SPECIFICATION	
3.4	Loss on drying (% w/w)		0.21	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)		99.8	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 (BDL Limit: 12)	Not more than 500		
	Acetone	BQL (BQL Limit: 8.0)	Not more than 500		
	Tetrahydrofuran	BDL (BDL Limit :4)	Not more than 500		
	Toluene	55	Not more than 500		

"BQL" indicates Below Quantification Limit.

"BDL" indicates Below Detection Limit.

Remarks: The material complies as per the Ph.Eur 11.4 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).

Note: Ensure material is packed under nitrogen atmosphere and tie properly whenever opening the bag/container.

	Prepared By QC	Checked By QC	Approved By QC
Signature & date	<u>M. P.</u> 03/05/24	<u>h</u> 03/05/24	<u>P</u> 03/05/24
Name	P. Murali	N. S. R. J. u.	G. S. Naidu
Designation	Executive	Jr. Manager	Sr. Manager

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