

2109000223

**Certificate of Analysis
(Re-Certified)**

R.L. Fine Chem Pvt. Ltd., Plot No. IP - 27 - 29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.- 561208. Contact No: 080-42488900,42488999.Fax No:080-28566630		
Product Name: AMITRIPTYLINE HYDROCHLORIDE Compendial Designation: USP /IHS		
Batch No: AMT/509		

Mfg. Date : JULY-2021

Retest Date : JUNE-2026

Date of Approval : 31.07.2021

TEST	OBSERVATION	SPECIFICATION	Reference to the test method
DESCRIPTION	White crystalline powder odorless	White or practically white. odorless or practically odorless crystalline powder or small crystals.	USP
SOLUBILITY	Complies	Freely soluble in water, in alcohol, in chloroform and in methanol: insoluble in ether.	USP
IDENTIFICATION:			
A) IR absorption spectrum	Sample spectrum is concordant with working standard spectrum	The IR spectrum of the sample should be concordant with that of the Amitriptyline hydrochloride working standard or reference standard spectrum	USP
B) HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	USP
C) Test for Chloride	Complies	A white curdy precipitate is formed	USP
pH	5.27	5.0 to 6.0	USP
LOSS ON DRYING	0.25 %	Not more than 0.5 %	USP
RESIDUE ON IGNITION	0.06 %	Not more than 0.1 %	USP
ORGANIC IMPURITIES (by HPLC)			
Amitriptyline related compound A	Below detection limit	Not more than 0.05 %	USP
Amitriptyline related compound B	Below detection limit	Not more than 0.15 %	
Nortriptyline	Below detection limit	Not more than 0.15 %	
Cyclobenzaprine	0.038 %	Not more than 0.15 %	
Any individual unspecified impurity	Below disregard limit	Not more than 0.10 %	
Total impurities	0.04 %	Not more than 1.0 %	

Prepared by

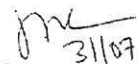
Checked by

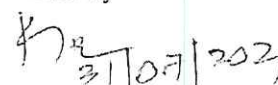
Approved by

Authorized by

 N. Lavanya
 31/07/2021


 31/07/2021


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 31/07/2021

Name : N Lavanya

Name : E. Radhika

Name : K. Pandian

Name : B. Krishna Murthy

Designation: Officer-QC

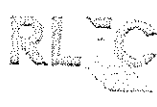
Designation: Officer-QC

Designation: AGM-QC

Designation: Asst. Manager-QA

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TEST	OBSERVATION	SPECIFICATION	Reference to the test method
ASSAY (by HPLC)	99.35 %	NLT 98.0 % and NMT 102.0 % calculated on the dried basis.	USP
RESIDUAL SOLVENTS(by GC)			
Methanol	Below detection limit	Not more than 1000 ppm	IHS
Tetrahydrofuran	Below detection limit	Not more than 500 ppm	
Toluene	90 ppm	Not more than 500 ppm	
Acetone	35 ppm	Not more than 1000 ppm	
Additional Test			
PARTICLE SIZE	58.863 µm	100 % < 80 Microns	IHS
Additional Test			
Total aerobic microbial count cfu/g	< 10 cfu/gm	Not more than 1000 cfu/gm	IHS
Total yeast and mould count cfu/g	< 10 cfu/gm	Not more than 100 cfu/gm	
Staphylococcus aureus/g	Absent/g	Should be absent	
E.coli/g	Absent/g	Should be absent	
Salmonella /10g	Absent/10g	Should be absent	
Pseudomonas aeruginosa/g	Absent/g	Should be absent	
Enterobacteriaceae	Absent/g	Should be absent	

Certification and Compliance statement

Certification and Compliance statements

The above material complies as per USP/IHS

Prepared by

Checked by

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Format No: QC F/(R3)100

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