


Certificate of Analysis

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

Batch No: ZPC/225011

Mfg. Date: FEBRUARY-2025

Retest Date: JANUARY-2030

Date of Approval: 18.02.2025

TEST	OBSERVATION	SPECIFICATION	Reference to the test method
Description	Slightly creamy white crystalline powder odorless.	White or slightly creamy white, odorless crystalline powder.	USP
Solubility	Complies	Very soluble in water, Freely soluble in alcohol and in chloroform; insoluble in ether and in benzene.	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 reference standard or working standard spectrum.	USP
B. Test for phenothiazines by TLC	Complies	The principle spot found in the test solution for other alkylated phenothiazines corresponds in R _F to the spot from the working standard solution.	USP
C. Test for chlorides	Complies	A white, curdy precipitate is formed	USP
Melting Range	196.2°C to 197.1°C	Between 195°C to 198°C	USP
Loss on drying (in % w/w)	0.33 %	Not more than 0.5	USP
Residue on ignition (in w/w)	0.05 %	Not more than 0.1	USP
Other alkylated phenothiazines by TLC (in %) Individual Impurity	Less than 0.5%	Not more than 0.5	USP
Assay by Potentiometry (in % w/w on dried basis)	100.4 %	Not less than 98.0 and Not more than 101.5	USP

Prepared by:

N Lavanya

Name: N Lavanya

Designation:
Executive-QC

GP.QCD.026/A01-1.0

Checked by:

Saddharma.B
18/02/25

Name: Saddharma.B

Designation:
Sr. Executive-QC

Approved by:

A Mohan Reddy
18/02/2025

Name: A Mohan Reddy

Designation:
Sr. Manager-QC

Authorized by:


G.V.Gopala Krishna Reddy
18/02/2025

Name: G.V.Gopala
Krishna Reddy

Designation:
Manager-QA

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TEST	OBSERVATION	SPECIFICATION	Reference to the test method
Related substances by HPLC (in %)			
(a). Impurity A	0.022 %	Not more than 0.10	IHS
(b). Impurity B	0.001 %	Not more than 0.10	
(c). Impurity C	0.016 %	Not more than 0.10	
(d). Impurity D	0.013 %	Not more than 0.10	
(e). Impurity E	Not detected	Not more than 0.10	
(f). Any unspecified impurity	0.021 %	Not more than 0.10	
(g). Total impurities	0.11 %	Not more than 1.0	
Residual solvents by GC (In ppm)			
(a). Toluene	5.4 ppm	Not more than 500	IHS
(b). Acetone	29 ppm	Not more than 2000	
(c). Isopropyl alcohol	106 ppm	Not more than 5000	

Certification and Compliance statements
 The above material complies as per USP /IHS

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