

Certificate of Analysis

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, Chickkabalapura Dist.- 561208. Contact No: 080-42488900,42488999.Fax No:080-28566630	
Product Name: TRIHEXYPHENIDYL HYDROCHLORIDE Compendial Designation: BP/IHS	

Batch No: THPHN/223001

Mfg. Date : JANUARY-2023

Retest Date : DECEMBER-2027

Date of Approval : 24.01.2023

TEST	OBSERVATION	SPECIFICATION	Reference to the test method
DESCRIPTION	White crystalline powder.	White or almost white, crystalline powder.	BP
SOLUBILITY	Complies	Slightly soluble in water, sparingly soluble in ethanol (96%) and in methylene chloride.	BP
Melting point	251.1°C	About 250°C, With decomposition.	BP
IDENTIFICATION:			
A) IR absorption spectrum	The IR absorption spectrum of the sample is concordant with that of working standard.	The IR absorption spectrum of the sample should be concordant with that of the Reference standard or working standard spectrum.	BP
B) Thin layer chromatography	Complies	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.	BP
C) Melting point after recrystallization	113.4°C	Melts about 113°C to 115°C	BP
D) Chloride test	A curdled, white precipitate is formed	A curdled, white precipitate is formed. It gives the reaction of chlorides.	BP
PH	5.60	5.2 to 6.2	BP
OPTICAL ROTATION	-0.0068°	-0.10° to +0.10°	BP
LOSS ON DRYING	0.20 %	Not more than 0.5 %	BP
SULPHATED ASH	0.05 %	Not more than 0.1 %	BP
ASSAY by Potentiometry	100.1 %	99.0% to 101.0 % (Calculated with Reference to the dried substance)	BP

Prepared by

Checked by

Approved by

Authorized by

24/01/23

Name : E.Radhika

Designation: Sr. Officer-QC

24/01/23

Name : Naveen.H.R

Designation: Executive-QC

24/01/23

Name : A.Mohan Reddy

Designation: Sr. Manager-QC

24/01/23

Name : Sarath Kumar.K

Designation: AGM-QA

Page 1 of 2



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TEST	OBSERVATION	SPECIFICATION	Reference to the test method
RELATED SUBSTANCE (BY HPLC)			
Impurity A	Below detection limit	Not more than 0.5%	BP
Unspecified impurity	Below disregard limit	Not more than 0.10%	
Total impurities	Below disregard limit	Not more than 0.5%	
RESIDUAL SOLVENTS (by GC)			
Methanol	42 ppm	Not more than 3000 ppm	IHS
Tetrahydrofuran	0.7 ppm	Not more than 720 ppm	
Toluene	1.8 ppm	Not more than 890 ppm	
Acetone	12 ppm	Not more than 5000 ppm	
Isopropyl alcohol	2.2 ppm	Not more than 5000 ppm	

Certification and Compliance statements

The above material complies as per BP/IHS

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Page 2 of 2

