
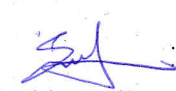


S. S. PHARMACHEM

PLOT NO: K-44/45 M.I.D.C, TARAPUR, BOISAR DIST. PALGHAR - 401 506,
MAHARASHTRA, INDIA. TEL.: 02525-205119 / 654243

Certificate of Analysis

Name of the Product	:	Diphenhydramine Hydrochloride USP			
Batch No.	:	SLL/DPH/0324022	Batch Size	:	980.100 Kg
Mfg. Date	:	MAR – 2024	A.R No.	:	001SL/24
Exp. Date	:	FEB – 2029	Date of Release	:	06/04/2024
Sr. No	Tests	Observations	Specification		
1.	Description	White, odorless crystalline powder.	White, odorless crystalline powder. Slowly darkens on exposure to light.		
2.	Litmus Test	Complies	Its solutions are practically neutral to litmus.		
3.	Solubility	Freely soluble in water, in chloroform and in alcohol; sparingly soluble in acetone, very slightly soluble in benzene and in ether.	Freely soluble in water; in chloroform and in alcohol; sparingly soluble in acetone, very slightly soluble in benzene and in ether.		
4.	Identification Tests A] IR Absorption	Complies	The IR absorption spectrum should be concordant with that of Diphenhydramine Hydrochloride working standard or reference standard.		
	B] Retention Time By HPLC	Complies	The retention time of the major peak of the sample solution corresponds to that of the standard solution.		
	C] Chloride Test	Complies	It gives reaction of chlorides.		
5.	Assay by HPLC (on dried basis)	100.1 % (O.D.B)	N.L.T 98.0% and N.M.T 102.0% (O.D.B)		
6.	Residue on Ignition	0.03%	Not more than 0.1%		
7.	Organic impurities by HPLC a) Diphenhydramine related compound A b) 4-Methyldiphenhydramine c) 4-Bromodiphenhydramine d) Benzhydrol e) Benzophenone f) Any other unspecified impurity g) Total impurities	BDL BDL BDL BDL BDL BDL BDL	a) Not more than 0.5% b) Not more than 0.3% c) Not more than 0.3% d) Not more than 0.3% e) Not more than 0.3% f) Not more than 0.10% g) Not more than 1.0%		
8.	Acidity & alkalinity (mL)	0.3 ml	Not more than 0.5 ml of 0.01 N sodium hydroxide required.		
9.	Loss on Drying	0.2%	Not more than 0.5%		
10.	Residual Solvents by GC-HSS	IPA – 111 ppm MCB – Not Detected 2-Chloropropane – 37 ppm	Isopropyl Alcohol : NMT 5000 ppm Monochlorobenzene : NMT 360 ppm 2-Chloropropane : NMT 360 ppm		
REMARK	:	The batch complies as per USP NF 2023.			
Analyst (QC Chemist)	:		Checked & Approved By (Q.C manager)	:	
Name	:	Bhakti Bari	Name	:	Sachin Gaikwad
Date	:	06 Apr. 2024	Date	:	06 Apr. 2024