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