

**SUPRIYA LIFESCIENCE LTD.**

Creating true values that bind global health

Certificate of analysis

Product	: Diphenhydramine Hydrochloride USP	License No.	: KD-129
Batch No.	: SLL/DPH/0220036	Date of Manufacturing	: Feb-2020
Batch Qty.	: 680.00kg	Date of re-test/Expiry	: Jan-2025
A. R. No.	: SLL/QC/FP/20/0241	Date of Release	: 25/02/2020

S.No.	Test	Specifications	Results
1.	Description	White, odorless, crystalline powder.	White crystalline powder, odorless
2.	Solubility	Freely soluble in water, in alcohol and in chloroform, sparingly soluble in acetone, very slightly soluble in benzene and in ether.	Conforms
3.	Identification:		
	i. IR Absorption	The IR absorption spectrum should be concordant with that of Diphenhydramine Hydrochloride working standard.	Complies
	ii. Retention time by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution.	Complies
	iii. Chloride test	Its gives reaction of chlorides	Complies
4.	Assay by HPLC on dry basis (%w/w)	Not less than 98.0 and Not more than 102.0	99.95
5.	Residue on ignition (%w/w)	Not more than 0.1	0.05
6.	Organic impurities by HPLC (%)		
	i. Diphenhydramine related compound A	Not more than 0.5	0.07
	ii. 4-Methyldiphenhydramine	Not more than 0.3	BDL
	iii. 4-Bromodiphenhydramine	Not more than 0.3	BDL
	iv. Benzhydrol	Not more than 0.3	BDL
	v. Benzophenone	Not more than 0.3	BDL
	vi. Any other unspecified impurity	Not more than 0.10	0.05
	vii. Total impurities	Not more than 1.0	0.12

QA/011/F03-02 / Effective date 05/08/2015

Page 1 of 2

Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai 400 063. Maharashtra, India.

Tel : +91 22 40332727 / 66942507 | Fax : +91 22 26860011

CIN: U51900MH2008PLC180452 | E-mail: supriya@supriyalifescience.com | Website: www.supriyalifescience.com**Factory**

: A-5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal. - Khed, Dist. - Ratnagiri, Pin: 415 722, Maharashtra, India.

Tel: +91 2356 272299 | Fax : +91 2356 272178 | E-Mail: factory@supriyalifescience.com

GOVT. RECOGNISED EXPORT HOUSE





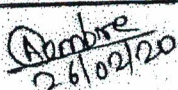
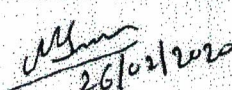
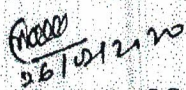
SUPRIYA LIFESCIENCE LTD.

Creating true values that bind global health

Certificate of analysis

Product	: Diphenhydramine Hydrochloride USP	License No.	: KD-129
Batch No.	: SLL/DPH/0220036	Date of Manufacturing	: Feb-2020
Batch Qty.	: 680.00kg	Date of re-test/Expiry	: Jan-2025
A. R. No.	: SLL/QC/FP/20/0241	Date of Release	: 25/02/2020

S.No.	Test	Specifications	Results
7.	Acidity or alkalinity (ml)	Not more than 0.5 ml of 0.01M sodium hydroxide required.	0.3
8.	Loss on drying @105°C for 3 hrs. (%w/w)	Not more than 0.5	0.16
9.	Additional test:		
9.1	Residual Solvents by GC-HS (ppm)		
	i. Isopropyl alcohol	Not more than 5000	270
	ii. Monochlorobenzene	Not more than 360	9
	iii. 2-Chloropropane	Not more than 5000	4
Remarks: The product complies with respect to above mentioned test as per USP41 Specifications.			
Where, BDL : Below Disregard Limit For Related Substances by HPLC			
Storage: Preserve in tight, light-resistant containers. Store at room temperature.			

 Compiled by QC QC Chemist (A.A.Ambre)	 Checked by QC QC Chemist (M.M.Sawant)	 Approved by Head – QC QC Head (S.H.Kambale)
--	---	--



QA/011/F03-02 / Effective date 05/08/2015

Page 2 of 2

Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai 400 063. Maharashtra, India.
Tel : +91 22 40332727 / 66942507 | Fax : +91 22 26860011
CIN: U51900MH2008PLC180452 | E-mail: supriya@supriyalifescience.com | Website: www.supriyalifescience.com

Factory : A-5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal.- Khed, Dist.- Ratnagiri, Pin: 415 722, Maharashtra, India.
Tel: +91 2356 272299 | Fax : +91 2356 272178 | E-Mail: factory@supriyalifescience.com

GOVT. RECOGNISED EXPORT HOUSE