

**SUPRIYA LIFESCIENCE LTD.**

Creating true values that binds global health

Certificate of Analysis

Product Name and grade	: Diphenhydramine Hydrochloride EP	Mfg. License No.	: KD-129
IUPAC Name	: 2-(Diphenylmethoxy)-N,N-dimethylethylamine hydrochloride.		
Batch No.	: SLL/DPH/0524064	CAS Number	: [147-24-0]
Batch Qty.	: 980.400 kg	Mfg. Date	: May - 2024
Dispatch Qty.	: 50.000 kg	Exp. / Retest Date	: Apr - 2029
A. R. No.	: SLL/QC/FP/24/1533	Date of release	: 30/05/2024

Sr.No.	Test	Specifications	Results
1.	Characters:		
1.1.	Appearance	White or almost white, crystalline powder.	White crystalline powder.
1.2.	Solubility	Very soluble in water, freely soluble in Ethanol (96%)	Conforms
2.	Identification : First identification C, D; Second identification A, B, D.		
2.1.	Test C: IR	The IR absorption spectrum should be concordant with that of Diphenhydramine Hydrochloride working standard/reference standard.	Complies
2.2.	Test D: Chlorides Test	It gives reaction (a) of chlorides.	Complies
3.	Tests		
3.1.	Appearance of solution (5.0%,w/v solution in water)	Solution S and a fivefold dilution of solution S are clear and solution S is not more intensely coloured than reference solution BY <sub>6</sub>	Solution S and a fivefold dilution of solution S are clear and solution S is less intensely coloured than reference solution BY <sub>6</sub>
3.2.	Acidity or alkalinity (mL)	Not more than 0.5 ml of 0.01M sodium hydroxide required to change the colour of indicator to yellow.	0.4
3.3.	Related Substances by HPLC (%)		
	Impurity A	Not more than 0.5	0.1
	Any other impurity	Not more than 0.3	0.1
	Total Impurities	Not more than 1.0	0.1
3.4.	Loss on drying @105°C (% w/w)	Maximum 0.5	0.2

SOP/SLL/QA/011/F03-05

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**Corporate Office :** 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai - 400 063. Maharashtra, India.  
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**GOVT. RECOGNISED EXPORT HOUSE**



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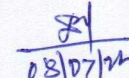
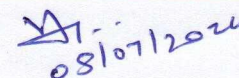
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Sr.No.	Test	Specifications	Results
3.5.	Sulfated ash (% w/w)	Maximum 0.1	0.01
3.6.	Assay on dry basis by potentiometrically (% w/w)	99.0 to 101.0	100.4
4.	Additional test		
4.1.	Residual Solvents by GC-HS(ppm)		
	Isopropyl alcohol	Not more than 5000	91
	Monochlorobenzene	Not more than 360	Not detected
	2-Chloropropane	Not more than 90	4

Where,

BDL: Below Disregard Limit For Related Substances by HPLC.

**Remarks:** The product complies with respect to above mentioned test as per grade **EP 11.0**.**Storage Condition :** Protected from light .

 08/07/24 Prepared by QA Officer (M.M.Ambre)	 08/07/24 Checked by QA Sr.Officer (D.B.Pol)	 08/07/2024 Approved by QA Sr.Executive (V.A.Sawant)
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