



Certificate of analysis

Product	: Chlorpheniramine Maleate Ph.Eur.	License No.	: KD-129
Batch No.	: SLL/C/0721101	Date of Manufacturing	: June-2021
Batch Qty.	: 1001.000 kg	Date of Expiry	: May-2026
A. R. No.	: SLL/QC/FP/21/0693	Date of Release	: 09/07/2021

Sr.No.	Test	Specifications	Results
1.	Characters:		
	i. Appearance	White or almost white, crystalline powder.	White crystalline powder.
	ii. Solubility	Freely soluble in water and soluble in ethanol (96%).	Conforms
2.	Identification:		
	i. Melting Point (°C)	130.0 to 135.0	134.7
	ii. IR Absorption	The IR absorption spectrum should be concordant with that of Chlorpheniramine Maleate working standard.	Complies
	iii. Optical rotation at 20°C (10.0%, w/v solution in water) (°)	-0.10° to +0.10°	-0.011
3.	Appearance of solution (10.0%, w/v solution in water)	Resultant solution should be clear and not more intensely coloured than reference solution BY ₆ .	Resultant solution is clear and less intensely coloured than reference solution BY ₆ .
4.	Optical rotation at 20°C (10.0%, w/v solution in water) (°)	-0.10 ° to +0.10 °	-0.011

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

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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 | Email: supriya@supriyalifescience.com | Website: www.supriyalifescience.com

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

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SUPRIYA LIFESCIENCE LTD.
Creating true values that binds global health

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Sr.No.	Test	Specifications	Results
5.	Related substances by HPLC (%)		
	i. Impurity A	Not more than 0.2	BDL
	ii. Impurity B	Not more than 0.1	BDL
	iii. Impurity C	Not more than 0.1	BDL
	iv. Impurity D	Not more than 0.1	BDL
	v. Unspecified Impurity	Not more than 0.10	BDL
	vi. Total Impurity	Not more than 0.5	BDL
6.	Loss on drying at 105°C for 4 h. (%,w/w)	Not more than 0.5	0.15
7.	Sulfated ash (%, w/w)	Not more than 0.1	0.06
8.	Assay on dry basis (%, w/w)	98.0 to 101.0	99.68
9.	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	BDL
	ii. Isopropanol	Not more than 5000	347
	iii. O-Xylene	Not more than 2170	BDL

Where,

BDL : Below Detection Limit For Residual Solvent by GC

BDL : Below Disregard Limit For Related Substances by HPLC

Remarks: The product complies with respect to above mentioned test as per **Ph.Eur 10.0** Specifications.

Storage: Protected from light.

 07/08/21 Compiled by QC QC Chemist (M.M.Sawant)	 07/08/21 Checked by QC QC Executive (S.A.Wakshe)	 07/08/21 Approved by - QC QC Dy.Sr.Manager (S.U.Takale)
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