

**SUPRIYA LIFESCIENCE LTD.**

Creating true values that binds global health

Certificate of analysis**R1-CEP 2008-154 – Rev 02**

Product Name and grade	: Chlorphenamine Maleate Ph.Eur.	License No.	: KD-129
Batch No.	: SLL/C/1222226	Month of Manufacturing	: Dec.- 2022
Batch Qty.	: 550.00 kg	Month of re-test / expiry	: Nov.- 2027
Dispatch Qty	: 25.00 kg		
A. R. No.	: SLL/QC/FP/22/2051	Date of Release	: 05/01/2023

Sr.No.	Test	Specifications	Results
I.	Characters:		
1.	Appearance	White or almost white, crystalline powder.	White crystalline powder.
2.	Solubility	Freely soluble in water and soluble in ethanol (96%).	Conforms
II.	Identification:		
1.	Test A : Melting Point (°C)	130.0 to 135.0	134.3
2.	Test B: IR	The infra red absorption spectrum should be concordant with that of Chlorphenamine Maleate working standard or reference standard.	Complies
3.	Test C: Optical rotation at 20°C (10.0%,w/v solution in water) (°)	-0.10° to +0.10°	-0.001
III.	Test:		
1.	Appearance of solution (10.0% ,w/v solution in water)	Solution S is clear and not more intensely coloured than reference solution BY ₆ .	Solution S is clear and less intensely coloured than reference solution BY ₆ .
2.	Optical rotation at 20°C (10.0%,w/v solution in water) (°)	-0.10 ° to +0.10 °	-0.001

QA/011/F03-03 /Effective date 15/12/2022

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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 | GSTIN : 27AALCS8686A1ZX
CIN : L51900MH2008PLC180452 | 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 672300 / 200 Fax : +91 2356 272178 E-Mail : factory@supriyalifescience.com

GOVT. RECOGNISED EXPORT HOUSE

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Sr.No.	Test	Specifications	Results
3.	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
4.	Loss on drying at 105°C for 4 h. (% w/w)	Maximum 0.5	0.16
5.	Sulfated ash (% w/w)	Maximum 0.1	0.03
6.	Assay on dry basis potentiometrically (% w/w)	98.0 to 101.0	100.16
IV.	Additional tests:		
1.	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	7
	ii. O-Xylene	Not more than 2170	38
	iii. Isopropyl alcohol	Not more than 5000	371
2.	DMC HCl BY GC-MS (ppm)	NMT 37.5	BLQ

Where,

BDL : Below Disregard Limit For Related Substances by HPLC

BLQ: Below limit Quantification

Remarks: The product complies with respect to above mentioned test as per grade Ph.Eur.10.**Storage Condition:** Protected from light.

 Prepared by QA Chemist (M.M.Ambre)	 Checked by QA Sr. Executive (V.A.Sawant)	 Approved by Head-QA/Designee Head-QA (Sheshhu Kumar Kalidindi)
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