

**SUPRIYA LIFESCIENCE LTD.**

Creating true values that binds global health

Certificate of analysis

Product	: Chlorpheniramine Maleate Ph.Eur.	License No.	: KD-129
Batch No.	: SLL/C/0119017	Date of Manufacturing	: Jan-2019
Batch Qty.	: 1000.00kg	Date of re-test/Expiry	: Dec-2023
A. R. No.	: SLL/QC/FP/19/0096	Date of Release	: 27/01/2019

S.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 to 135	134.2
	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	+0.013
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	+0.013

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

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S.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.	Heavy metals (ppm)	Not more than 20	Less than 20
7.	Loss on drying at 105°C for 4 h. (% w/w)	Not more than 0.5	0.16
8.	Sulfated ash (% w/w)	Not more than 0.1	0.04
9.	Assay on dry basis (% w/w)	98.0 to 101.0	99.12
10.	Additional test:		
10.1	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	BDL
	ii. Isopropanol	Not more than 5000	739
	iii. O-Xylene	Not more than 2170	26
Remarks: The product is complies with respect to above mentioned test as per Ph.Eur. 9.6 specifications.			
Storage: Protected from light.			
Ambre 27/02/19 Compiled by QC QC Chemist (A.A.Ambre)		27/02/19 Checked by QC Dy. Sr. Manager (S.U. Takale)	
		27/02/19 Approved by QC QC Head (S.H.Kambale)	