

**SUPRIYA LIFESCIENCE LTD.***Creating true values that bind global health***Certificate of analysis**

CEP NO. : R1-CEP 2008-154-Rev 01

Product	: Chlorpheniramine Maleate Ph.Eur	License No.	: KD-129
Batch No.	: SLL/C/0117013	Date of Manufacturing	: Jan -2017
Batch Qty.	: 1000.0 kg	Date of re-test/Expiry	: Dec -2021
A. R. No.	: SLL/QC/FP/17/0032	Date of Release	: 14/01/2017

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	134.5
	ii. IR Absorption	The IR absorption spectrum should be concordant with that of Chlorpheniramine Maleate working standard.	Positive
	iii. Optical rotation at 20°C (10.0%, w/v solution in water) (°)	-0.10 to +0.10	+0.008
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 not more 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	+0.008

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

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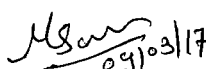
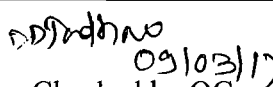
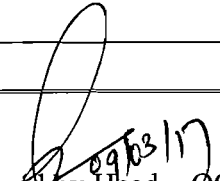
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S.No.	Test	Specifications	Results
5.	Related substances by HPLC (%)		
	i. Impurity A	Not more than 0.2	BDL
	ii. Impurity B	Not more than 0.1	BDL
	iii. Impurity C	Not more than 0.1	BDL
	iv. Impurity D	Not more than 0.1	BDL
	v. Unspecified Impurity	Not more than 0.10	BDL
	vi. Total Impurity	Not more than 0.5	0.05
6.	Loss on drying at 105°C for 4 h. (% ,w/w)	Not more than 0.5	0.13
7.	Sulfated ash (% , w/w)	Not more than 0.1	0.05
8.	Assay on dry basis (% , w/w)	98.0 to 101.0	99.57
9.	Additional test:		
	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	BDL
	ii. Isopropanol	Not more than 5000	636
	iii. O-Xylene	Not more than 2170	19
Remarks: <i>The product is complies with respect to above mentioned test as per Ph.Eur. 9.0 specifications.</i>			
Storage: <i>Protected from light.</i>			
 Compiled by QC QC Chemist (M.M.Sawant)		 Checked by QC QC Executive (D.D.Jadhav)	
 Approved by Head – QC QC Dy.Sr.Manager (S.U.Takale)			