

**SUPRIYA LIFESCIENCE LTD.**

(Formerly known as Supriya Chemicals)

Certificate of analyses

Product	:	Chlorpheniramine Maleate Ph. Eur.	Customer	:	M/s. Oceanic Pharmachem Pvt Ltd.
Batch No.	:	SLL/C/0314044	License No.	:	KD-129
Batch Qty.	:	1000.0 kg	Date of Manufacturing	:	Mar, 2014
Dispatch Qty.	:	25.0kg	Date of re-test/Expiry	:	Feb, 2019
A. R. No.	:	SLL/QC/FP/14/0214	Date of Release	:	15/03/2014

S.No.	Test	Specifications	Results
1.	Characters:		
	i. Appearance	White or almost white, crystalline powder.	A 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	134.1
	ii. IR Absorption	The IR absorption spectrum should be concordant with that of Chlorpheniramine Maleate working standard.	Positive
	iii. Optical Rotation (°) @20 °C (10.0% ,w/v solution in water)	-0.10 to +0.10	+0.01
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 <sub>6</sub> .	Resultant solution is clear and not more intensely coloured than reference solution BY <sub>6</sub> .
4.	Optical Rotation (°) @20 °C (10.0% ,w/v solution in water)	-0.10 to +0.10	+0.01

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

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: A 5/2, Lote Parshuram Industrial Area, M.I.D.C, Tal. - Khed, Dist.-Ratnagiri, 415 722, Maharashtra, India.

Tel. : +91 2356 272299

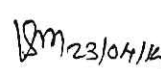
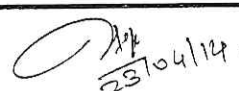
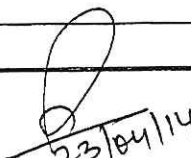
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S.No.	Test	Specifications	Results
5.	Related substance by HPLC (%)		
	i. Impurity A	Not more than 0.2	Not Detected
	ii. Impurity B	Not more than 0.1	Not Detected
	iii. Impurity C	Not more than 0.1	Not Detected
	iv. Impurity D	Not more than 0.1	Not Detected
	v. Unspecified Impurity	Not more than 0.10	Below disregard limit
	vi. Total Impurity	Not more than 0.5	0.05
6.	Heavy metals (ppm)	Not more than 20	Less than 20
7.	Loss on drying @105°C for 4 hrs. (% w/w)	Not more than 0.5	0.19
8.	Sulfated ash (% w/w)	Not more than 0.1	0.04
9.	Assay on dry basis (% w/w)	98.0 to 101.0	99.21
10.	<b>Additional test:</b>		
	Residual solvent by GC-HS (ppm)		
	i. Methanol	Not more than 3000	450
	ii. Isopropanol	Not more than 5000	Not Detected
	iii. O-Xylene	Not more than 2170	Not Detected
<b>Remarks:</b> The product is complies with respect to above mentioned test as per Ph.Eur.8.0 specifications.			
<b>Storage:</b> Protected from light.			
 Compiled by QC		 Checked by QC	
		 Approved by Head - QC	

QA/011/F06-00/Effective date 01/01/2014

FAGRON IBERICA, S.A.U  
Corresponde al lote de Fagron:

JYE 12 - B04

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