

Certificate of analysis

Product	: Diphenhydramine Hydrochloride Ph.Eur	License No.	: KD-129
Batch No.	: SLL/DPH/1016095	Date of Manufacturing	: Oct -2016
Batch Qty.	: 1105.0 kg	Date of re-test/Expiry	: Sept -2021
A. R. No.	: SLL/QC/FP/16/0823	Date of Release	: 14/10/2016

S.No.	Test	Specifications	Results
1.	Characters:		
	i. Appearance	White or almost white, crystalline powder.	A white crystalline powder
	ii. Solubility	Very soluble in water, freely soluble in alcohol	Conforms
2.	Identification:		
	i. Melting Point (°C)	168 to 172	169.3
	ii. UV absorption	The ratio of the absorbance measured at the maximum at 258 nm to that measured at the maximum at 253 nm should be 1.1 to 1.3. The ratio of the absorbance measured at the maximum at 258 nm to that measured at the maximum at 264 nm should be 1.2 to 1.4.	1.2 1.3
	iii. IR Absorption	The IR absorption spectrum should be concordant with that of Diphenhydramine Hydrochloride working standard.	Positive
	iv. Chlorides	It gives reaction of chlorides.	Positive
3.	Appearance of solution (5.0%,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 .



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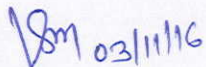
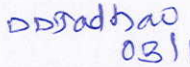

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S.No.	Test	Specifications	Results
4.	Acidity or alkalinity (ml)	Not more than 0.5 ml of 0.01M sodium hydroxide required.	0.2
5.	Related Substance by HPLC (%)		
	i. Impurity A	Not more than 0.5	BDL
	ii. Any other impurity	Not more than 0.3	0.09
	iii. Total Impurities	Not more than 1.0	0.17
6.	Loss on drying @105°C (% w/w)	Not more than 0.5	0.17
7.	Sulfated ash (% w/w)	Not more than 0.1	0.03
8.	Assay on dry basis (% w/w)	99.0 to 101.0	100.74
9.	Additional test:		
	Residual Solvents by GC-HS (ppm)		
	i. Isopropyl alcohol	Not more than 5000	249
	ii. Monochlorobenzene	Not more than 360	4
	iii. 2-Chloropropane	Not more than 5000	10

Remarks: The product is complies with respect to above mentioned test as per Ph.Eur 8.0 specifications.

Storage: Protected from light.

 Compiled by QC QC Chemist (V.S. Mahabal)	 Checked by QC QC Executive (D.D. Jadhav)	 Approved by - QC QC Head (S.H. Kambale)
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