

**WANBURY****Certificate of Analysis**

Product	: Diphenhydramine Hydrochloride Ph. Eur	Batch No	: DH02060814
Mfg, date	: Aug, 2014	Retest Date	: Jul, 2019
Quantity	: 125 Kg	No. of Containers	: 05
Customer Name	: FAGRON SERVICES B.V, NETHERLANDS		

S. No	Test	Result	Specification
1	Description	White crystalline powder	White or almost white, crystalline powder
2	Solubility	Complies	Very soluble in water, freely soluble in alcohol.
3	Identification		
	Melting Point	169.7°C	168°C to 172°C
	UV	1.2	The ratio of absorbance measured at the maximum at 258nm and 253nm is 1.1 to 1.3
		1.3	The ratio of absorbance measured at the maximum at 258nm and 264nm is 1.2 to 1.4
	IR Spectrum	Concordant	Shall concordant the spectrum obtained with Diphenhydramine HCl working standard
	Test for chlorides	Complies	Should be positive
4	Appearance of solution	Complies	5% solution in water and fivefold dilution of solution are clear and solution not more intensely colored than reference solution BY <sub>6</sub>
5	Acidity or alkalinity	0.2 mL	Not more than 0.5ml of 0.01M sodium hydroxide is consumed for 10ml of 5% solution in water
6	Related substances (By HPLC)		
	Impurity A	0.06 %	Not more than 0.5 %
	Any other Impurity	0.12 %	Not more than 0.3 %
	Total of all Impurities	0.32 %	Not more than 1.0 %
7	Loss on drying	0.09 %	Not more than 0.5 %
8	Sulfated ash	0.05 %	Not more than 0.1 %
9	Assay (on dry basis)	99.6 %	99.0 % to 101.0 %
<b>Additional Tests</b>			
10	Residual solvents		
	Isopropyl alcohol	171 ppm	Not more than 2000 ppm
	Monochloro benzene	79 ppm	Not more than 300 ppm

Remarks: The product complies with Ph. Eur &amp; as per the customer specifications.

Prepared by

Executive-QC

Date: 23/08/14

Reviewed by

Manager-QC

Date: 23/08/14

Approved by

Dy. Manager-QA

Date: 23/08/14

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

14K7-B03

Director Técnico

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