

| Certificate of Analysis | | | |
|-------------------------|---|-------------------|--------------|
| Product | : Diphenhydramine Hydrochloride Ph. Eur | Batch No | : DH00780415 |
| Mfg. date | : Mar, 2015 | Retest Date | : Feb, 2020 |
| Quantity | : 125 Kg | No. of Containers | : 05 |
| Customer Name | : FAGRON SERVICES B.V, NETHERLANDS | | |

| S. No | Test | Result | Specification |
|-------------------------|------------------------------|---------------------------------|--|
| 1 | Description | Almost white crystalline powder | White or almost white, crystalline powder |
| 2 | Solubility | Complies | Very soluble in water, freely soluble in alcohol. |
| 3 | Identification | | |
| | Melting Point | 169.5°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 ₆ |
| 5 | Acidity or alkalinity | 0.3 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 | 0.08 % | Not more than 0.5 % |
| | Any other Impurity | 0.12 % | Not more than 0.3 % |
| | Total of all Impurities | 0.29 % | Not more than 1.0 % |
| 7 | Loss on drying | 0.18 % | Not more than 0.5 % |
| 8 | Sulfated ash | 0.04 % | Not more than 0.1 % |
| 9 | Assay (on dry basis) | 99.4 % | 99.0 % to 101.0 % |
| Additional Tests | | | |
| 10 | Residual solvents | | |
| | Isopropyl alcohol | 495 ppm | Not more than 2000 ppm |
| | Monochloro benzene | Below Detectable Limit | Not more than 300 ppm |

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

Prepared by

[Signature]

Reviewed by

[Signature]

Approved by

[Signature]

Executive-QC

Date: 11/04/15

Dy. Manager-QC

Date:

11/04/15

Dy. Manager-QA

Date:

11/04/15

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

15227-007

Director Técnico

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