# Certificate of Analysis

| | | | | | |
|---|---|---|---|---|---|
| Product Name and grade | : | Diphenhydramine Hydrochloride EP | Mfg. License No. | : | KD-129 |
| IUPAC Name | : | 2-(Diphenylmethoxy)-N,N-dimethylethylamine hydrochloride. | | | |
| Batch No. | : | SLL/DPH/0524064 | CAS Number | : | [147-24-0] |
| Batch Qty. | : | 980.400 kg | Mfg. Date | : | May - 2024 |
| Dispatch Qty. | : | 50.000 kg | Exp. / ~~Retest~~ Date | : | Apr - 2029 |
| A. R. No. | : | SLL/QC/FP/24/1533 | Date of release | : | 30/05/2024 |

| Sr.No. | Test | Specifications | Results |
|---|---|---|---|
| 1. | Characters: | | |
| 1.1. | Appearance | White or almost white, crystalline powder. | White crystalline powder. |
| 1.2. | Solubility | Very soluble in water, freely soluble in Ethanol (96%) | Conforms |
| 2. | Identification : First identification C, D; Second identification A, B, D. | | |
| 2.1. | Test C: IR | The IR absorption spectrum should be concordant with that of Diphenhydramine Hydrochloride working standard/reference standard. | Complies |
| 2.2. | Test D: Chlorides Test | It gives reaction (a) of chlorides. | Complies |
| 3. | Tests | | |
| 3.1. | Appearance of solution (5.0%,w/v solution in water) | Solution S and a fivefold dilution of solution S are clear and solution S is not more intensely coloured than reference solution $BY_6$ | Solution S and a fivefold dilution of solution S are clear and solution S is less intensely coloured than reference solution $BY_6$ |
| 3.2. | Acidity or alkalinity (mL) | Not more than 0.5 ml of 0.01M sodium hydroxide required to change the colour of indicator to yellow. | 0.4 |
| 3.3. | Related Substances by HPLC (%) | | |
| | Impurity A | Not more than 0.5 | 0.1 |
| | Any other impurity | Not more than 0.3 | 0.1 |
| | Total Impurities | Not more than 1.0 | 0.1 |
| 3.4. | Loss on drying @105°C (%, w/w) | Maximum 0.5 | 0.2 |



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**CIN : L51900MH2008PLC180452** I Email: supriya@supriyalifescience.com I Website: www.supriyalifescience.com

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GOVT. RECOGNISED EXPORT HOUSE

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| Sr.No. | Test | Specifications | Results |
|---|---|---|---|
| 3.5. | Sulfated ash (%, w/w) | Maximum 0.1 | 0.01 |
| 3.6. | Assay on dry basis by potentiometrically (%, w/w) | 99.0 to 101.0 | 100.4 |
| 4. | Additional test | | |
| 4.1. | Residual Solvents by GC-HS(ppm) | | |
| | Isopropyl alcohol | Not more than 5000 | 91 |
| | Monochlorobenzene | Not more than 360 | Not detected |
| | 2-Chloropropane | Not more than 90 | 4 |

Where,
BDL: Below Disregard Limit For Related Substances by HPLC.

**Remarks:** The product complies with respect to above mentioned test as per grade **EP 11.0.**

**Storage Condition :** Protected from light .

| Prepared by QA | Checked by QA | Approved by QA |
|---|---|---|
| 08/07/24 | 08/07/24 | 08/07/2024 |
| Officer (M.M.Ambre) | Sr.Officer (D.B.Pol) | Sr.Executive (V.A.Sawant) |



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