CAG PHARMACHEM PVT.LTD.



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GSTIN: 27AAICC6203E1ZZ

**CERTIFICATE OF ANALYSIS**

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|  |  |
| --- | --- |
| **Name of Product** | **(11Z)-11-[3-(Dimethylamino)propylidene]-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid hydrochloride** |
| **Batch No.** | **CAG/OHC/01/23** |
| **Mfg.Date** | **SEP - 2023** |
| **Exp.Date** | **AUG - 2028** |

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| --- | --- | --- | --- |
| **Sr.No.** | **PARAMETERS** | **SPECIFICATIONS** | **RESULTS** |
| **1** | **Description** | **A White to almost white crystalline powder** | **White crystalline Powder** |
| **2** | **Solubility** | **Very soluble in formic acid , sparingly in water, very slightly soluble in dehydrated alcohol** | **Complies** |
| **3** | **Identification** |  |  |
|  | 1. **By IR** | **The IR absorption spectrum of substance being examined in KBr disc should be concordant with the IR spectrum obtained from Olopatadine Hcl ws** | **Complies** |
|  | 1. **By HPLC** | **The retention time of the major peak of the sample preparation of that of the standard solution, as obtained in the Assay by HPLC** | **Complies** |
|  | 1. **Chloride Test** | **Comply Test** | **Complies** |
| **4** | **PH** | **Between 2.0 to 4.0 at 25 oC** | **2.95** |
| **5** | **Heavy Metals (ppm )** | **NMT 10 ppm** | **Complies** |
| **6** | **Loss on drying**  **(At 105 Deg.C for 3Hr)** | **NMT 0.3% w/w** | **0.13%** |

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| **Sr.No.** | **PARAMETERS** | **SPECIFICATIONS** | **RESULTS** |
| **7** | **Related Substances by HPLC ( %, w/w )**   1. **Alpha – hydroxy olopatadine** 2. **Olopatadine E- isomer** 3. **Any unknown individual impurity**   **d) Total impurities** | **NMT 0.2%**  **NMT 0.1%**  **NMT 0.1%**  **NMT 0.26%** | **NOT DETECTED**  **0.07%**  **0.04 %**  **0.11%** |
| **8** | **Sulphated ash** | **NMT 0.1%w/w** | **0.06%** |
| **9** | **Assay by HPLC** | **Not less than 98.00% and Not more than 102% w/w on dried basis** | **99.91%** |
| **10** | **Residual Solvents by GC (ppm )**   1. **Toluene** 2. **Acetone** 3. **Methanol** 4. **THF** 5. **MDC** | **NMT 890 ppm**  **NMT 5000ppm**  **NMT 3000ppm**  **NMT 720ppm**  **NMT 600ppm** | **45 ppm**  **730ppm**  **95.12ppm**  **ND**  **ND** |

**Remark: product Batch No. CAG/OHC/01/23 complies as per specification.**

**ANALYZED BY:** CHECKED BY: