CAG PHARMACHEM PVT.LTD.

H.No.1115, Murti, Tal.Baramati, Dist.Pune.413102

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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** |

|  |  |  |  |
| --- | --- | --- | --- |
| **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: