

# CERTIFICATE OF ANALYSIS

(Certificate No. KMO003022-01)

Release Date: 05/04/2024

Re-test Date: 04/04/2027

## Oxcarbazepine EP Impurity K

### Identification

**Chemical Name :**

N-Formyl-10-oxo-10,11-dihydro-5H-dibenzo[b,f]azepine-5-carboxamide (as per EP & USP)

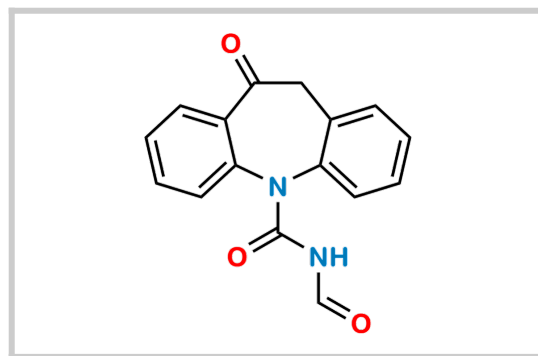
**Alt. Name** : Oxcarbazepine USP Related compound A

**CAT No.** : KMO003022

**CAS No.** : 1346601-76-0

**Molecular Formula** : C<sub>16</sub>H<sub>12</sub>N<sub>2</sub>O<sub>3</sub>

**Molecular Weight** : 280.3



### Analytical Information

**Batch No.** : OXC-N-FORMYL-019-237

**Solubility** : Methanol

**Description** : Off White Solid

**Mass** : Confirm

**HPLC Purity** : 94.40 %

**IR** : Confirm

**Weight Loss By TGA** : 0.17 %

**<sup>1</sup>H NMR** : Confirm

**% Potency** : 94.24 %

### Additional Information

**Long Term Storage** : Store at 2-8 deg. C for long term storage

**Shipping Condition** : Product is stable to be Shipped at Room Temperature

**% Potency** = [100 - 0.17(Weight Loss By TGA)] x [94.40(HPLC Purity)]/100 = 94.24 %

-Re-tested on 05.04.2024

**Recommendation** : Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 22/08/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 22/08/2024 |

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA