

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)

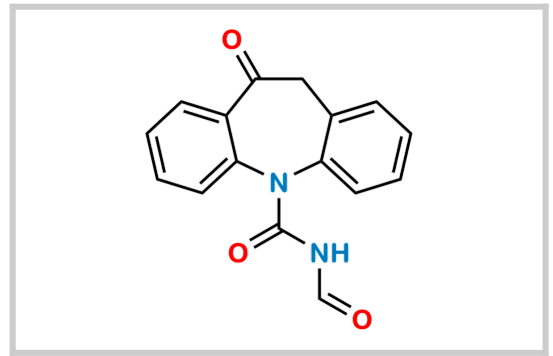
Alt. Name : Oxcarbazepine USP Related compound A

CAT No. : KMO003022

CAS No. : 1346601-76-0

Molecular Formula : C₁₆H₁₂N₂O₃

Molecular Weight : 280.3



Analytical Information

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

Description : Off White Solid

HPLC Purity : 94.40 %

Weight Loss By TGA : 0.17 %

% Potency : 94.24 %

Solubility : Methanol

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

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, ¹H NMR, IR and TGA