

CERTIFICATE OF ANALYSIS

(Certificate No. KMO024006-01)

Release Date: 09/10/2024

Re-test Date: 08/10/2027

N-Nitroso-N-Desmethyl Olopatadine Impurity

Identification

Chemical Name :

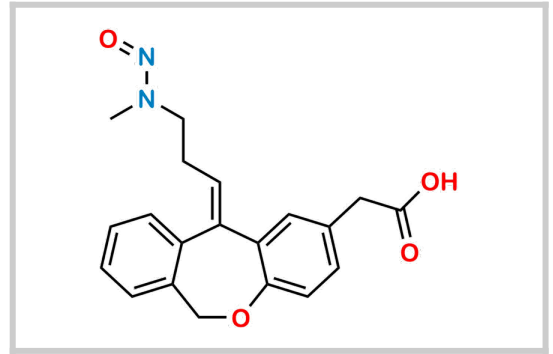
2-(11-(3-(methyl(nitroso)amino)propylidene)-6,11-dihydrodibenzo[b,e]oxepin-2-yl)acetic acid (Mixture of E/Z Isomer)

CAT No. : KMO024006

CAS No. : Not Available

Molecular Formula : C₂₀H₂₀N₂O₄

Molecular Weight : 352.4



Analytical Information

Batch No. : O024006-073-408

Description : Yellow Solid

HPLC Purity : 97.42 %

Weight Loss By TGA : 0.28 %

% Potency : 97.15 %

Solubility : Acetonitrile

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 = $[100 - 0.28(\text{Weight Loss By TGA})] \times [97.42(\text{HPLC Purity})]/100 = 97.15 \%$

-Mixture of Isomer

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		09/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		09/10/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA