

CERTIFICATE OF ANALYSIS

(Certificate No. KMT002001-01)

Release Date: 20/02/2024

Re-test Date: 19/02/2027

N-Nitroso Tranexamic Acid EP Impurity A

Identification

Chemical Name :

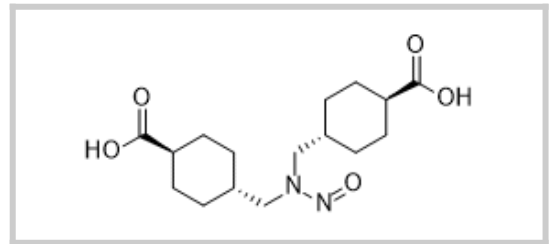
(1R,1'R,4r,4'r)-4,4'-((nitrosoazanediyl)bis(methylene))dicyclohexanecarboxylic acid (Mixture of E/Z Isomer)

CAT No. : KMT002001

CAS No. : Not Available

Molecular Formula : C₁₆H₂₆N₂O₅

Molecular Weight : 326.39



Analytical Information

Batch No. : TRA-EPA-N-NO-073-080

Solubility : ACN

Description : Off White Solid

Mass : Confirm

HPLC Purity : 96.90 %

IR : Confirm

Weight Loss By TGA : 0.34 %

¹H NMR : Confirm

% Potency : 96.57 %

¹³C 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 - 0.34(Weight Loss By TGA)] x [96.90(HPLC Purity)]/100 = 96.57 %
-Mixture of Isomers

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 20/02/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 20/02/2024 |

Attachments : COA, SER, HPLC, MASS, ¹HNMR, ¹³CNMR, IR and TGA