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

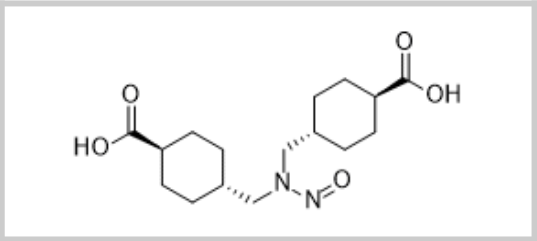
Chemical Name :
(1R,1'R,4r,4'r)-4,4'-((nitrosoazanediyl)bis(methylene))dicyclohexanecarboxylic acid (Mixture of E/Z Isomer)

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		06/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/01/2025

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