

CERTIFICATE OF ANALYSIS

(Certificate No. KMV001001-01)

Release Date: 31/01/2024

Re-test Date: 30/01/2027

N-Nitroso of Impurity-A

Identification

Chemical Name :

N-(2-(1-hydroxycyclohexyl)-2-(4-methoxyphenyl)ethyl)-N-methyl nitrous amide (Mixture of E/Z Isomers)

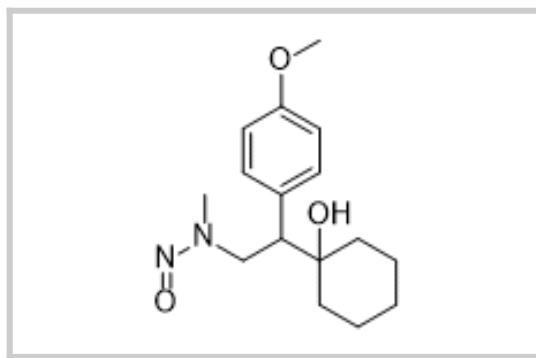
Alt. Name : N-Nitroso Venlafaxine EP Impurity D

CAT No. : KMV001001

CAS No. : 2680662-11-5

Molecular Formula : C₁₆H₂₄N₂O₃

Molecular Weight : 292.37



Analytical Information

Batch No. : VEN-EPD-NO-073-058

Solubility : Acetonitrile*

Description : Light Yellow Thick Syrup

Mass : Confirm

HPLC Purity : 99.98 %

IR : Confirm

Weight Loss By TGA : 2.46 %

¹H NMR : Confirm

% Potency : 97.52 %

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 - 2.46(Weight Loss By TGA)] x [99.98(HPLC Purity)]/100 = 97.52 %

Remarks : COA Re-generated on 11.04.2024

-Mixture of Isomers

* Freely soluble in Methanol & Insoluble in Water (Additional solubility data added on 16.07.2024)

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh patel		16/07/2024
Reviewed & Approved By	Quality Control	Jatin patel		16/07/2024

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