

# 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)

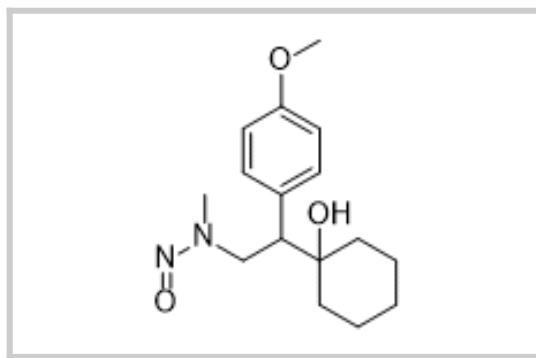
**Alt. Name** : N-Nitroso Venlafaxine EP Impurity D

**CAT No.** : KMV001001

**CAS No.** : 2680662-11-5

**Molecular Formula** : C<sub>16</sub>H<sub>24</sub>N<sub>2</sub>O<sub>3</sub>

**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 %

**<sup>1</sup>H 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
<b>Prepared By</b>	Analytical	Jignesh patel		16/07/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin patel		16/07/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA