

# CERTIFICATE OF ANALYSIS

(Certificate No. KMD015001-01)

Release Date: 20/12/2024

Re-test Date: 19/12/2027

## N-Nitroso Desmethyl Diltiazem

### Identification

**Chemical Name :**

(2S,3S)-2-(4-methoxyphenyl)-5-(2-(methyl(nitroso)amino)ethyl)-4-oxo-2,3,4,5-tetrahydrobenzo[b][1,4]thiazepin-3-yl acetate (Mixture of E/Z Isomers)

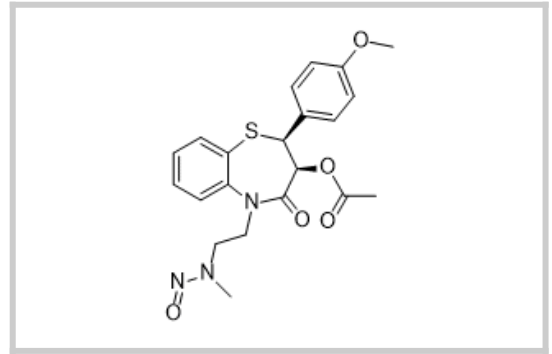
**Alt. Name** : N-Nitroso Diltiazem EP Impurity D

**CAT No.** : KMD015001

**CAS No.** : Not Available

**Molecular Formula** : C<sub>21</sub>H<sub>23</sub>N<sub>3</sub>O<sub>5</sub>S

**Molecular Weight** : 429.49



### Analytical Information

**Batch No.** : D015001-091-093

**Description** : Yellow Solid

**HPLC Purity** : 99.47 %

**Weight Loss By TGA** : 0.15 %

**% Potency** : 99.32 %

**Solubility** : Acetonitrile

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 0.15(Weight Loss By TGA)] x [99.47(HPLC Purity)]/100 = 99.32 %

-Mixture of Isomer

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		01/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/01/2025

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