

CERTIFICATE OF ANALYSIS

(Certificate No. KMD015001-01)

Release Date: 28/05/2024

Re-test Date: 27/05/2027

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)

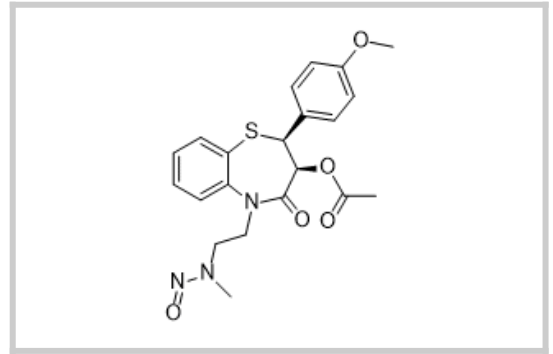
Alt. Name : N-Nitroso Diltiazem EP Impurity D

CAT No. : KMD015001

CAS No. : Not Available

Molecular Formula : C₂₁H₂₃N₃O₅S

Molecular Weight : 429.49



Analytical Information

Batch No. : DIL-EPD-NO-073-244

Description : Yellow Solid

HPLC Purity : 99.56 %

Weight Loss By TGA : 1.77 %

% Potency : 97.8 %

Solubility : ACN

Mass : Confirm

IR : Confirm

¹H 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 - 1.77(Weight Loss By TGA)] x [99.56(HPLC Purity)]/100 = 97.8 %

-Mixture of Isomers

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/05/2024
Reviewed & Approved By	Quality Control	Jatin Patel		28/05/2024

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