

CERTIFICATE OF ANALYSIS

(Certificate No. KMT001001-01)

Release Date: 29/01/2024

Re-test Date: 28/01/2027

N-Nitroso Theophylline EP Impurity D

Identification

Chemical Name :

N-methyl-4-(methyl(nitroso)amino)-1H-imidazole-5-carboxamide

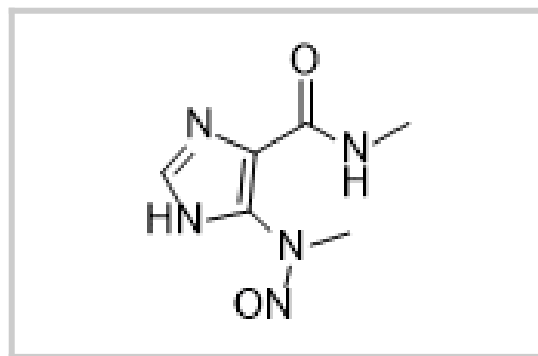
Alt. Name : N-Nitroso Theophyllidine

CAT No. : KMT001001

CAS No. : Not Available

Molecular Formula : C₆H₉N₅O₂

Molecular Weight : 183.17



Analytical Information

Batch No. : THE-EPD-NO-073-047

Solubility : Acetonitrile

Description : Light Green Solid

Mass : Confirm

HPLC Purity : 99.85 %

IR : Confirm

Weight Loss By TGA : 0.40 %

¹H NMR : Confirm

% Potency : 99.45 %

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 - 0.40(Weight Loss By TGA)] x [99.85(HPLC Purity)]/100 = 99.45 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------|
| Prepared By | Analytical | Jignesh patel | | |
| Reviewed & Approved By | Quality Control | Jatin patel | | |

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