# CERTIFICATE OF ANALYSIS

(Certificate No. KMT188019-01)

**Release Date:** 25/03/2026 **Re-test Date:** 24/03/2029

## N-Nitroso Trimebutine Impurity 1

## Identification

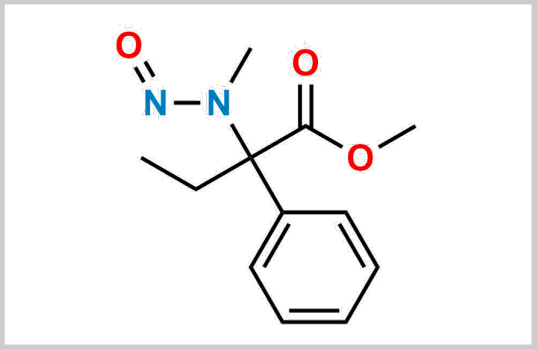
**Chemical Name** :
Methyl 2-(methyl(nitroso)amino)-2-phenylbutanoate

**CAT No.** : KMT188019

**CAS No.** : Not Available

**Molecular Formula** : C12H16N2O3

**Molecular Weight** : 236.3




## Analytical Information

| | | | |
|---|---|---|---|
| **Batch No.** | : T188019-114-225 | **Solubility** | : ACN |
| **Description** | : Light Yellow Thick Syrup | **Mass** | : Confirm |
| **HPLC Purity** | : 99.08 % | **IR** | : Confirm |
| **Weight Loss By TGA** | : 0.35 % | **1H NMR** | : Confirm |
| **% Potency** | : 98.73 % | | |

## 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 - 0.35(Weight Loss By TGA)] x [99.08(HPLC Purity)]/100 = 98.73 %

**Recommendation** : Released

| | Department | Name | Signature | Date |
|---|---|---|---|---|
| **Prepared By** | Analytical | Jignesh Patel | | 25/03/2026 |
| **Reviewed & Approved By** | Quality Control | Jatin Patel | | 25/03/2026 |

**Attachments** : COA, HPLC, MASS, 1HNMR, IR and TGA