

# CERTIFICATE OF ANALYSIS

(Certificate No. KMM091007-01)

Release Date: 05/12/2024

Re-test Date: 04/12/2027

## Metformin Impurity E

### Identification

**Chemical Name :**  
1-Methyl Biguanide

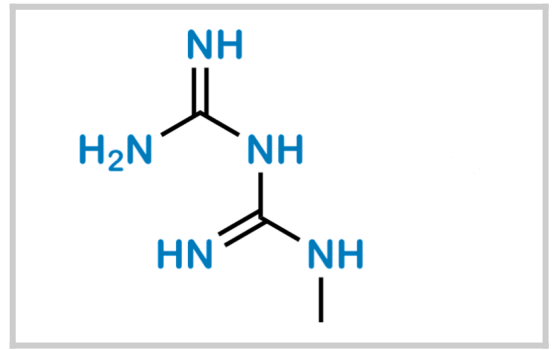
**Alt. Name :** Metformin USP Related Compound B  
; N-Desmethyl Metformin

**CAT No. :** KMM091007

**CAS No. :** 1609-00-3

**Molecular Formula :** C<sub>3</sub>H<sub>9</sub>N<sub>5</sub>

**Molecular Weight :** 115.1



### Analytical Information

**Batch No. :** M091007-091-066

**Description :** White Solid

**HPLC Purity :** 97.90 %

**Weight Loss By TGA :** 0.01 %

**% Potency :** 97.89 %

**Solubility :** Water

**Mass :** Confirm

**IR :** Confirm

**<sup>1</sup>H NMR :** Confirm

**<sup>13</sup>C 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 - 0.01(Weight Loss By TGA)] x [97.90(HPLC Purity)]/100 = 97.89 %

**Recommendation :** Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 05/12/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 05/12/2024 |

**Attachments :** COA, HPLC, MASS, <sup>1</sup>H NMR, <sup>13</sup>C NMR, IR and TGA