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

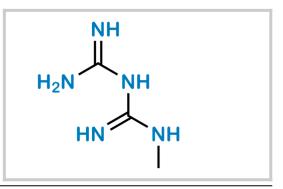
; N-Desmethyl Metformin

CAT No. : KMM091007

CAS No. : 1609-00-3

Molecular Formula : C3H9N5

Molecular Weight : 115.1



Analytical Information

Batch No. : M091007-091-066 **Solubility** : Water Description : White Solid Mass : Confirm **HPLC Purity** : 97.90 % IR : Confirm : Confirm Weight Loss By TGA : 0.01 % 1H NMR % Potency : 97.89 % **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 - 0.01(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, 1HNMR, 13CNMR, IR and TGA