

CERTIFICATE OF ANALYSIS

(Certificate No. KMG042007-01)

Release Date: 25/03/2026

Re-test Date: 24/03/2029

Gliclazide EP Impurity B

Identification

Chemical Name :
2-Nitroso-octahydrocyclopenta[c]pyrrole

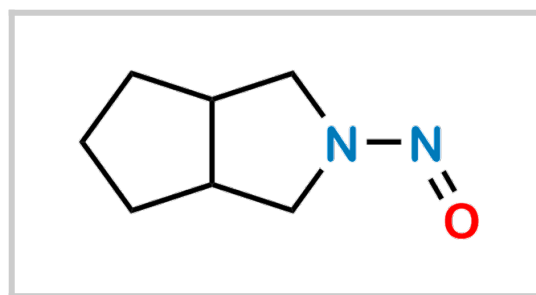
Alt. Name : Gliclazide BP Impurity B

CAT No. : KMG042007

CAS No. : 54786-86-6

Molecular Formula : C₇H₁₂N₂O

Molecular Weight : 140.2



Analytical Information

Batch No. : G042007-114

Description : Light Yellow Liquid

HPLC Purity : NLT 95.1 %

Weight Loss By TGA : NLT 0.1 %

% Potency : 95 %

Solubility : Acetonitrile

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 - 0.1(Weight Loss By TGA)] x [95.1(HPLC Purity)]/100 = 95 %

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, LC-MS, Mass, ¹H NMR, IR and TGA