CERTIFICATE OF ANALYSIS

(Certificate No. KMI036007-01)

Release Date: 26/09/2025 **Re-test Date:** 25/09/2028

Indapamide EP Impurity A

Identification

Chemical Name :
(2RS)-2-Methyl-1-nitroso-2,3-dihydro-1H-indole

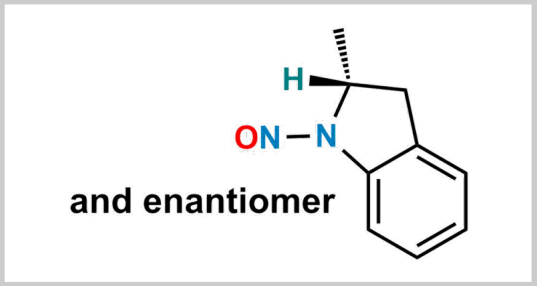
Alt. Name : Indapamide USP Related Compound D

CAT No. : KMI036007

CAS No. : 85440-79-5

Molecular Formula : C9H10N2O

Molecular Weight : 162.2



Analytical Information

Batch No. : I036007-102

Description : Off white solid

HPLC Purity : NLT 95.1 %

Weight Loss By TGA : NLT 0.1 %

% Potency : 95 %

Solubility : Acetonitrile : Water (1:1)

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		26/09/2025
Reviewed & Approved By	Quality Control	Jatin Patel		26/09/2025

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