## **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

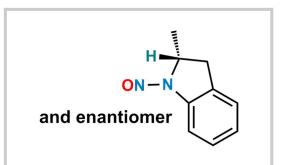
**Alt. Name** : Indapamide USP Related Compound

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**CAT No.** : KMI036007 **CAS No.** : 85440-79-5

Molecular Formula : C9H10N2O

**Molecular Weight** : 162.2



### **Analytical Information**

**Description** : Off white solid

HPLC Purity : NLT 95.1 %

Weight Loss By TGA : NLT 0.1 %

1H NMR : Confirm

**% Potency** : 95 %

#### **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** =  $[100 - 0.1(Weight Loss By TGA)] \times [95.1(HPLC Purity)]/100 = 95 %$ 

**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