

CERTIFICATE OF ANALYSIS

(Certificate No. KMI017088-01)

Release Date: 21/08/2024

Re-test Date: 20/08/2027

N-Nitroso Ibrutinib Impurity 1

Identification

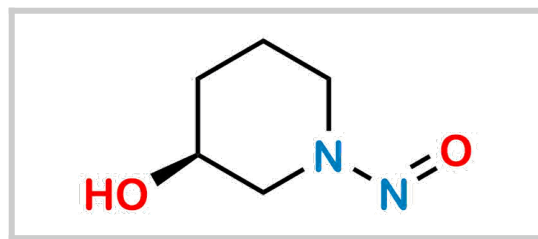
Chemical Name :
(S)-1-Nitrosopiperidin-3-ol

CAT No. : KMI017088

CAS No. : 2380680-64-6

Molecular Formula : C₅H₁₀N₂O₂

Molecular Weight : 130.1



Analytical Information

Batch No. : IBR-IMP-1-NO-073-345

Description : Light Yellow Liquid

HPLC Purity : 99.83 %

Weight Loss By TGA : 1.97 %

% Potency : 97.86 %

Solubility : Methanol

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 - 1.97(Weight Loss By TGA)] x [99.83(HPLC Purity)]/100 = 97.86 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		21/08/2024
Reviewed & Approved By	Quality Control	Jatin Patel		21/08/2024

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