CERTIFICATE OF ANALYSIS

(Certificate No. KMI017089-01)

Release Date: 21/08/2024 **Re-test Date:** 20/08/2027

N-Nitroso Ibrutinib Impurity 2

Identification

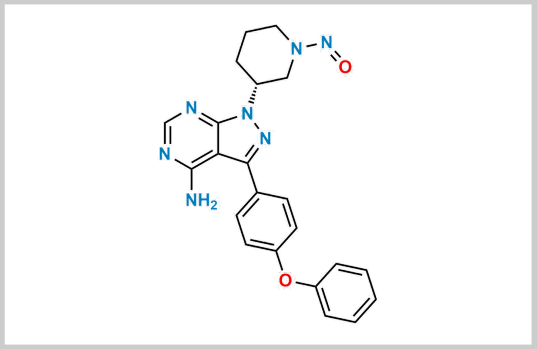
Chemical Name :
(R)-1-(1-Nitrosopiperidin-3-yl)-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4-d]pyrimidin-4-amine

CAT No. : KMI017089

CAS No. : Not Available

Molecular Formula : C22H21N7O2

Molecular Weight : 415.5



Analytical Information

Batch No. : IBR-IMP-2-NO-073-346

Description : Off White Solid

HPLC Purity : 99.77 %

Weight Loss By TGA : 0.22 %

% Potency : 99.55 %

Solubility : ACN : Methanol (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 - 0.22(Weight Loss By TGA)] x [99.77(HPLC Purity)]/100 = 99.55 %

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