

CERTIFICATE OF ANALYSIS

(Certificate No. KMA043048-01)

Release Date: 29/10/2024

Re-test Date: 28/10/2027

Acalabrutinib Nitroso Impurity 2

Identification

Chemical Name :

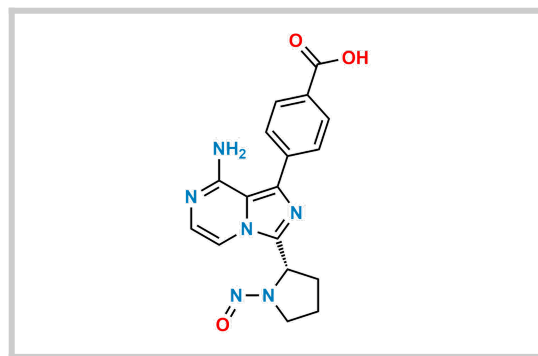
(S)-4-(8-Amino-3-(1-nitrosopyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)benzoic acid (Mixture of E/Z Isomer)

CAT No. : KMA043048

CAS No. : Not Available

Molecular Formula : C₁₇H₁₆N₆O₃

Molecular Weight : 352.4



Analytical Information

Batch No. : A043048-091-014

Description : Light Yellow Solid

HPLC Purity : 97.01 %

Weight Loss By TGA : 2.93 %

% Potency : 94.17 %

Solubility : ACN : 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 - 2.93(Weight Loss By TGA)] x [97.01(HPLC Purity)]/100 = 94.17 %
-Mixture of Isomer

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		30/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		30/10/2024

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