CERTIFICATE OF ANALYSIS

(Certificate No. KMA043048-01)

Release Date: 29/10/2024 **Re-test Date:** 28/10/2027

Acalabrutinib Nitroso Impurity 2

Identification

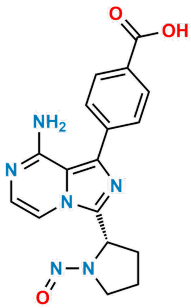
Chemical Name :
(S)-4-(8-Amino-3-(1-nitrosopyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)benzoic acid (Mixture of E/Z Isomer)

CAT No. : KMA043048

CAS No. : Not Available

Molecular Formula : C17H16N6O3

Molecular Weight : 352.4



Analytical Information

Batch No.	: A043048-091-014	**Solubility**	: ACN : Water (1:1)
Description	: Light Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 97.01 %	**IR**	: Confirm
Weight Loss By TGA	: 2.93 %	**1H NMR**	: Confirm
% Potency	: 94.17 %		

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