

CERTIFICATE OF ANALYSIS

(Certificate No. KMA009001-01)

Release Date: 08/04/2024

Re-test Date: 07/04/2027

N-Nitroso Desethyl Amiodarone

Identification

Chemical Name :

N-(2-(4-(2-butylbenzofuran-3-carbonyl)-2,6-diiodophenoxy)ethyl)-N-ethylnitrous amide (Mixture of E/Z Isomer)

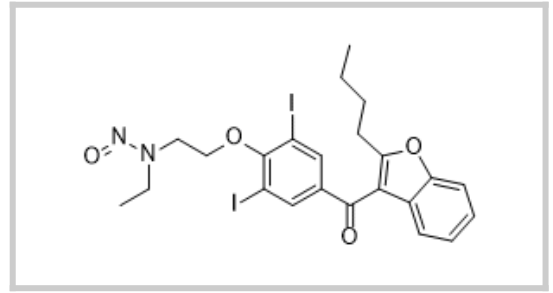
Alt. Name : N-Nitroso Amiodarone EP Impurity B

CAT No. : KMA009001

CAS No. : 678982-38-2

Molecular Formula : C₂₃H₂₄I₂N₂O₄

Molecular Weight : 646.26



Analytical Information

Batch No. : AMI-N-NO-045-182

Solubility : ACN

Description : Light Yellow Thick Syrup

Mass : Confirm

HPLC Purity : 98.70 %

IR : Confirm

Weight Loss By TGA : 1.17 %

¹H NMR : Confirm

% Potency : 97.55 %

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 = $[100 - 1.17(\text{Weight Loss By TGA})] \times [98.70(\text{HPLC Purity})]/100 = 97.55 \%$

Remarks : COA Re-generated on 22.05.2024

-Re-purified and Re-tested on 21.05.2024

-Mixture of Isomers

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/05/2024
Reviewed & Approved By	Quality Control	Jatin Patel		22/05/2024

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