

# 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)

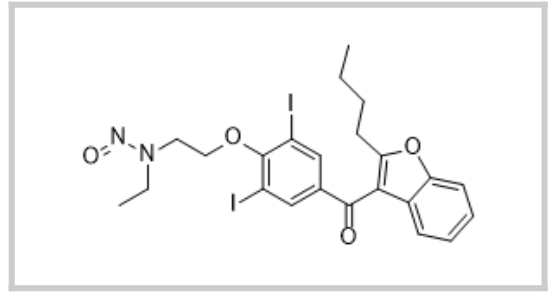
**Alt. Name** : N-Nitroso Amiodarone EP Impurity B

**CAT No.** : KMA009001

**CAS No.** : 678982-38-2

**Molecular Formula** : C<sub>23</sub>H<sub>24</sub>I<sub>2</sub>N<sub>2</sub>O<sub>4</sub>

**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 %

**<sup>1</sup>H 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, <sup>1</sup>HNMR, IR and TGA