

# **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)

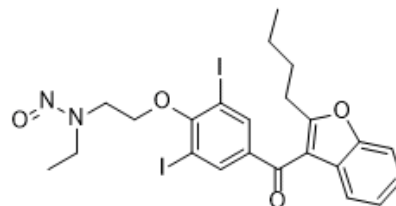
**Alt. Name** : N-Nitroso Amiodarone EP Impurity B

**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(Weight Loss By TGA)] x [98.70(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