CERTIFICATE OF ANALYSIS

(Certificate No. KMA009001-01)

Release Date: 08/04/2024 **Re-test Date:** 07/04/2027

N-Nitroso Desethyl Amiodarone

Identification

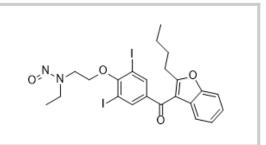
Chemical Name:

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

Alt. Name : N-Nitroso Amiodarone EP Impurity B

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(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, 1HNMR, IR and TGA