CERTIFICATE OF ANALYSIS

(Certificate No. KMA009001-01)

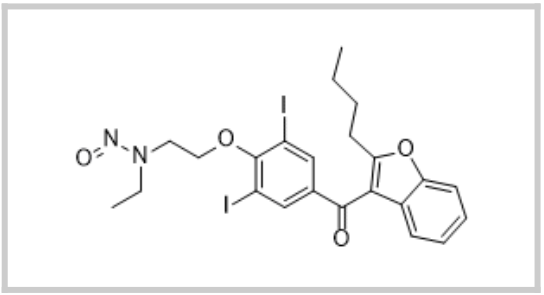
Release Date: 08/04/2024 **Re-test Date:** 07/04/2027

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(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