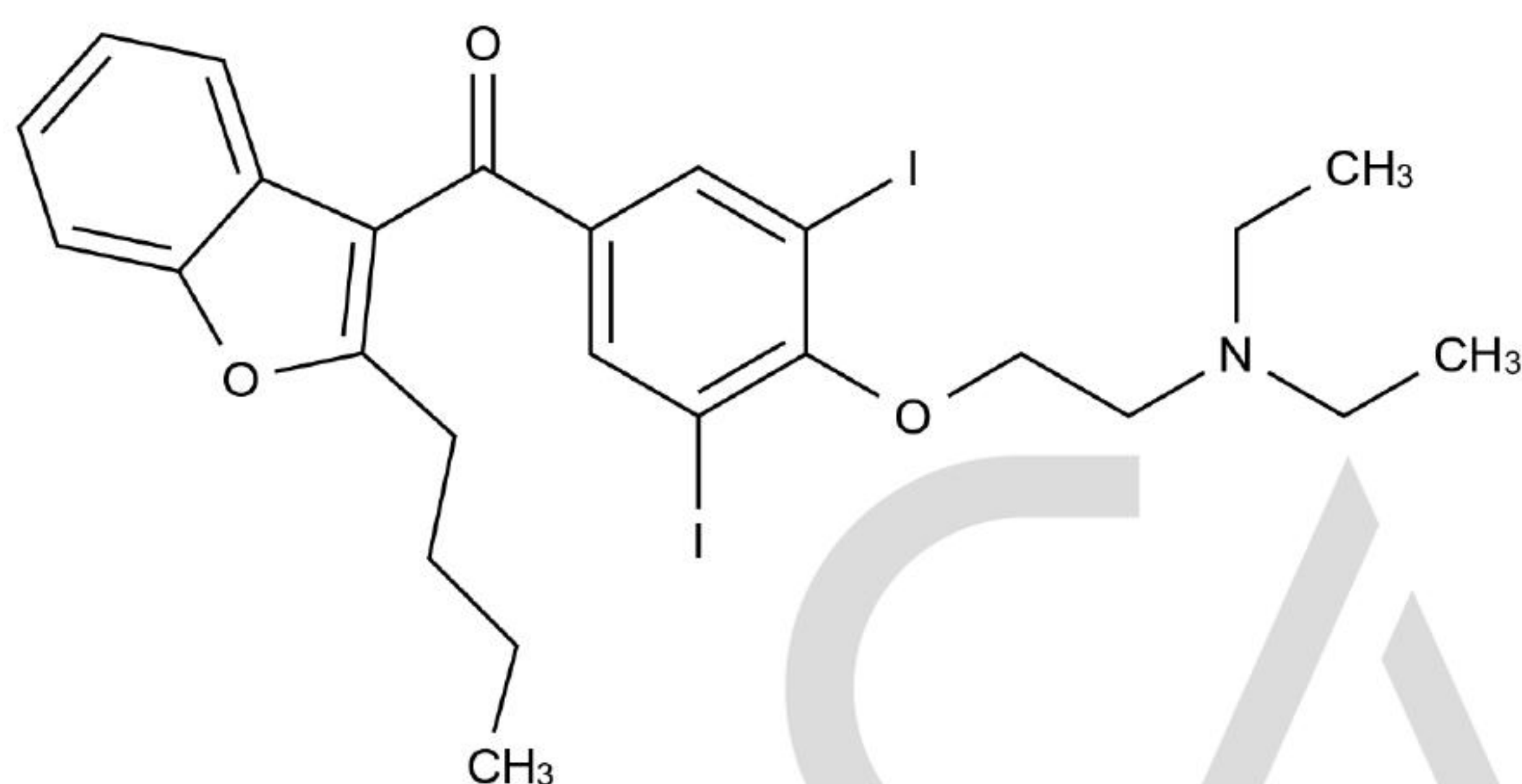


Certificate of Analysis

Reference Material & Standard

Product Name:	Amiodarone	Catalogue Number:	CCAD303493
Synonyms:	N/A	Lot Number:	0625-RE-0063
CAS Number:	1951-25-3	Expiry Date:	Jun 26, 2027
Molecular Formula:	C ₂₅ H ₂₉ I ₂ NO ₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	645.31		
Chemical Structure:			



Warning:



Test Items	Method	Results
Appearance	Visual inspection	White Sticky Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.635%
Loss On Drying	TGA	0.0593%
Assay		98.6%
Uncertainty		±2.0%

Comment:

1. The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Loss On Drying}) * \text{Purity HPLC (\%)} / 100\%$$

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

2. The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

Prepared by: 古雪

Reviewed by:

Lisa

Aproved by General Manager:

David

Date: Jun 28, 2023

Date: Jun 28, 2023

Date: Jun 28, 2023

