

CERTIFICATE OF ANALYSIS

(Certificate No. KMA009011-01)

Release Date: 23/06/2026

Re-test Date: 22/06/2029

Amiodarone Impurity E

Identification

Chemical Name :

(2-Butylbenzofuran-3-yl)(4-hydroxyphenyl)methanone (as per EP) ; (2-Butylbenzofuran-3-yl)(4-hydroxyphenyl) methanone (as per USP)

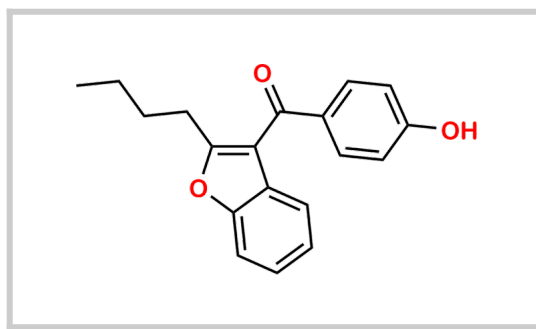
Alt. Name : Amiodarone USP Related Compound E

CAT No. : KMA009011

CAS No. : 52490-15-0

Molecular Formula : C₁₉H₁₈O₃

Molecular Weight : 294.3



Analytical Information

Batch No. : A009011-136-055

Description : Off White Solid

HPLC Purity : 97.71 %

Weight Loss By TGA : 0.40 %

% Potency : 97.32 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

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 - 0.40(Weight Loss By TGA)] x [97.71(HPLC Purity)]/100 = 97.32 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 23/06/2026 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 23/06/2026 |

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA