



Via Curiel 34, 20067 Paullo (MI) - ITALY

Tel.: +39 02 90 62 60.1

Cambrex Profermaco Milano S.r.L.

### Certificate of Analysis

|                 |                          |           |                 |
|-----------------|--------------------------|-----------|-----------------|
| Product         | AMIODARONE HYDROCHLORIDE | C.A.S. n. | 19774-82-4      |
| Batch           | 760106                   | Formula   | C25H29I2NO3.HCl |
| Production date | October 2018             | M.W.      | 681.8           |
| Expiration Date | September 2023           | T.S.      | 016.013         |
| Analysis        | October 17 2018          |           |                 |
| Coa Number      | CA7.607                  |           |                 |

| DETERMINATION              | SPECIFICATION                            | RESULT               |
|----------------------------|------------------------------------------|----------------------|
| DESCRIPTION                | White crystalline powder, odourless      | COMPLIES             |
| SOLUBILITY                 | Methylene chloride                       | Clear solution       |
| APPEARANCE OF SOLUTION     | Methanol                                 | Clear and NMCT GY5   |
| COLOR                      | Abs. at 420 nm in Methanol               | NMT 0.100            |
| IDENTIFICATIONS            | IR spectrum                              | Conforms to standard |
|                            | Chlorides                                | Positive             |
| RESIDUE ON IGNITION        |                                          | NMT 0.1 %            |
| HEAVY METALS               |                                          | NMT 20 ppm           |
| LOSS ON DRYING             |                                          | NMT 0.5 %            |
| WATER                      |                                          | NMT 0.5 %            |
| PH                         |                                          | 3.2 / 3.8            |
| IODIDES                    |                                          | NMT 150 ppm          |
| IMPURITY H BY TLC          | Diethylaminoethylchloride HCl (EP/USP-H) | NMT 0.01 %           |
| RELATED SUBSTANCES BY HPLC | Diiodo butyl (EP/USP-D)                  | NMT 0.200 %          |
|                            | Mono iodo Amiodarone (EP/USP-C)          | NMT 0.100 %          |
|                            | Bis desiodo Amiodarone (EP/USP-A)        | NMT 0.100 %          |
|                            | Any unspecified impurity                 | NMT 0.100 %          |
|                            | Total unspecified impurities             | NMT 0.300 %          |
|                            | Total impurities                         | NMT 0.500 %          |
| ASSAY                      | By titration (on dried basis)            | 98.5 / 101.0 %       |
|                            | Assay by HPLC (on dried basis)           | 98.5 / 101.0 %       |
| RESIDUAL SOLVENTS BY GLC   | Etanol                                   | NMT 2000 ppm         |
|                            | Acetone                                  | NMT 50 ppm           |
|                            | Chloroform                               | NMT 50 ppm           |
|                            | Methylene Chloride                       | NMT 100 ppm          |

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICHQ7)

The product conforms to requirements of: USP  
41/EUPH 9

Approved by Qualified Person / Quality Director  
Laura Bigini  
10-17-2018

This Certificate of Analysis has been approved by the Qualified Person / Quality Director and produced automatically with validated electronic signature