

*02/06/2025*

**CERTIFICATE OF ANALYSIS**

**PRODUCT : AMIODARONE HYDROCHLORIDE EP**

CAS No. : 19774-82-4

Batch No. : 25AM000053

Inspection Lot No : 40000051433

Mfg. Date : February 2025

Quantity Supplied : 5.0 Kg

Expiry Date : January 2030

Date of Release : 09/03/2025

S.No.	Tests	Observations	Specifications	Method Reference
1.	Description	White fine crystalline powder.	White or almost white, fine crystalline powder	Ph.Eur
2.	Solubility	Very slightly soluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96%).	Very slightly soluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96%).	Ph.Eur
3.	Identification By IR	Infrared spectrum of the test is Concordant with the infrared spectrum of the standard obtained in the same manner.	Infrared spectrum of the test should Concordant with the infrared spectrum of the standard obtained in the same manner.	Ph. Eur. <2.2.24>
4.	Identification By reaction of chloride	A white curdy precipitate is form, which insoluble in nitric acid and dissolves in excess of ammonia.	A white curdy precipitate should be form, which insoluble in nitric acid and dissolves in excess of ammonia.	Ph.Eur<2.3.1>
5.	Appearance of solution (5%w/v solution in Methanol)	The solution is clear and less intensely coloured than reference solution GY <sub>5</sub> and BY <sub>5</sub> .	The solution should be clear and not more intensely coloured than reference solution GY <sub>5</sub> or BY <sub>5</sub> .	Ph.Eur<2.2.1> Ph.Eur<2.2.2, Method II>
6.	pH (5%w/v solution in water)	3.3	Between 3.2 and 3.8	Ph.Eur<2.2.3>
7.	Impurity H (%w/w, by TLC)	Less than 0.02	Not more than 0.02	Ph.Eur<2.2.27>
8.	Related substances (%w/w, by HPLC) Ph. Eur.impurity C	Not detected	Not more than 0.2	Ph.Eur<2.2.29>
9.	Related substances (%w/w, by HPLC) Ph. Eur.impurity D	Below detection limit	Not more than 0.2	Ph.Eur<2.2.29>

Prepared by	Checked by	Approved by
<i>05/05/2025</i>	<i>05/05/2025</i>	<i>05/05/2025</i>
<b>Sandip Girase</b>	<b>Chakradhar Patil</b>	<b>Chetan Modi</b>
<b>Sr. Officer – QA</b>	<b>Jr. Executive – QA</b>	<b>Manager – QA</b>

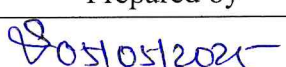
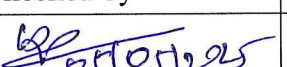
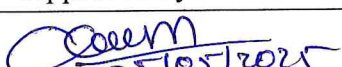
### CERTIFICATE OF ANALYSIS

<b>PRODUCT : AMIODARONE HYDROCHLORIDE EP</b>			
CAS No.	: 19774-82-4		
Batch No.	: 25AM000053	Inspection Lot No	: 40000051433
Mfg. Date	: February 2025	Quantity Supplied	: 5.0 Kg
Expiry Date	: January 2030	Date of Release	: 09/03/2025

S.No.	Tests	Observations	Specifications	Method Reference
10.	Related substances (%w/w, by HPLC) Ph. Eur. impurity G	Below detection limit	Not more than 0.2	Ph.Eur<2.2.29>
11.	Related substances (%w/w, by HPLC) Unspecified impurity	Below reporting threshold	Not more than 0.10	Ph.Eur<2.2.29>
12.	Related substances (%w/w, by HPLC) Total impurities	Not detected	Not more than 0.5	Ph.Eur<2.2.29>
13.	Loss on drying (% w/w, in vacuo at 50 °C for 4 hours)	0.17	Not more than 0.5	Ph.Eur<2.2.32>
14.	Sulphated ash (% w/w, determined on 1.0 g)	0.04	Not more than 0.1	Ph.Eur<2.4.14>
15.	Assay (by titrimetry, % as C <sub>25</sub> H <sub>29</sub> I <sub>2</sub> NO <sub>3</sub> , HCl, on dried basis)	100.4	Not less than 98.5 and Not more than 101.0	Ph.Eur<2.2.20>
16.	Iodides by UV (ppm)	Less than 150	Not more than 150	Ph.Eur
17.	Residual solvent (µg/g, by GC) Methanol	Not detected	Not more than 1000	In house
18.	Residual solvent (µg/g, by GC) Ethanol	Not detected	Not more than 1000	In house
19.	Residual solvent (µg/g, by GC) Isopropyl alcohol	637	Not more than 2000	In house
20.	Residual solvent (µg/g, by GC) Toluene	Below detection limit	Not more than 890	In house
21.	Residual solvent (µg/g, by GC) Benzene*	Not detected	Not more than 2	In house

\*Benzene is not used in process. Since it may be probable contaminant of other process solvent, the limit of residual Benzene is incorporated in the COA.

**Remark: The Product Complies to above Specifications.**

Prepared by	Checked by	Approved by
		
<b>Sandip Girase</b>	<b>Chakradhar Patil</b>	<b>Chetan Modi</b>
<b>Sr. Officer – QA</b>	<b>Jr. Executive – QA</b>	<b>Manager – QA</b>