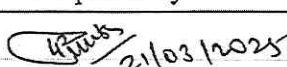
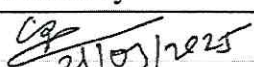
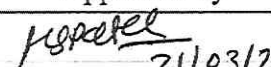


## CERTIFICATE OF ANALYSIS

<b>PRODUCT : AMIODARONE HYDROCHLORIDE EP</b>	
CAS No. : 19774-82-4	
Batch No. : 25AM000040	Inspection Lot No : 40000051397
Mfg. Date : February 2025	Quantity Supplied : 6.0 kg
Expiry Date : January 2030	Date of Release : 08/03/2025

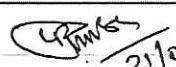
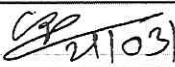
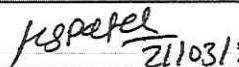
S.No.	Tests	Observations	Specifications	Method Reference
1.	Description	White fine crystalline powder.	White or almost white, fine crystalline powder	Ph.Eur
2.	Solubility	Very slightly soluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96%).	Very 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	Paper moistened with Diphenylcarbazine solution turns violet red.	Paper moistened with Diphenylcarbazine solution should be turns violet red.	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 A	Not detected	Not more than 0.2	In house
9.	Related substances (%w/w, by HPLC) Ph. Eur.impurity B	0.02	Not more than 0.2	In house
10.	Related substances (%w/w, by HPLC) Ph. Eur.impurity C	Below detection limit	Not more than 0.2	In house

Prepared by	Checked by	Approved by
 21/03/2025	 21/03/2025	 21/03/2025
<b>Chhatrasinh Girase</b>	<b>Chakradhar Patil</b>	<b>Hemant Patel</b>
<b>Assistant – QA</b>	<b>Jr. Executive - QA</b>	<b>Dy. Manager – QA</b>

**CERTIFICATE OF ANALYSIS**

<b>PRODUCT : AMIODARONE HYDROCHLORIDE EP</b>			
CAS No.	: 19774-82-4		
Batch No.	: 25AM000040	Inspection Lot No	: 40000051397
Mfg. Date	: February 2025	Quantity Supplied	: 6.0 kg
Expiry Date	: January 2030	Date of Release	: 08/03/2025

S.No.	Tests	Observations	Specifications	Method Reference
11.	Related substances (%w/w, by HPLC) Ph. Eur.impurity D	0.04	Not more than 0.2	In house
12.	Related substances (%w/w, by HPLC) Ph. Eur.impurity E	Not detected	Not more than 0.2	In house
13.	Related substances (%w/w, by HPLC) Ph. Eur.impurity F	Not detected	Not more than 0.2	In house
14.	Related substances (%w/w, by HPLC) Ph. Eur.impurity G	Below limit of quantification	Not more than 0.2	In house
15.	Related substances (%w/w, by HPLC) Any impurity	0.03	Not more than 0.10	In house
16.	Related substances (%w/w, by HPLC) Total impurities	0.09	Not more than 0.5	In house
17.	Loss on drying (% w/w, determined on 1.0 g by drying at 50 °C at a pressure not exceeding 0.3 kPa for 4 hrs.)	0.13	Not more than 0.5	Ph.Eur<2.2.32>
18.	Sulphated ash (% w/w, determined on 1.0 g)	0.04	Not more than 0.1	Ph.Eur<2.4.14>
19.	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>

Prepared by	Checked by	Approved by
 21/03/2025	 21/03/2025	 21/03/2025
<b>Chhatrasinh Girase</b>	<b>Chakradhar Patil</b>	<b>Hemant Patel</b>
<b>Assistant – QA</b>	<b>Jr. Executive - QA</b>	<b>Dy. Manager – QA</b>



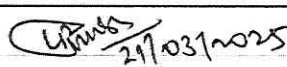
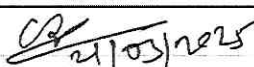
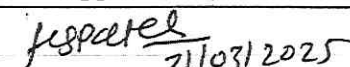
**CERTIFICATE OF ANALYSIS**

<b>PRODUCT : AMIODARONE HYDROCHLORIDE EP</b>	
CAS No. : 19774-82-4	
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S.No.	Tests	Observations	Specifications	Method Reference
20.	Iodides by UV (ppm)	Less than 150	Not more than 150	Ph.Eur
21.	Residual solvent (µg/g, by GC) Methanol	Not detected	Not more than 1000	In house
22.	Residual solvent (µg/g, by GC) Ethanol	Not detected	Not more than 1000	In house
23.	Residual solvent (µg/g, by GC) Isopropyl alcohol	444	Not more than 2000	In house
24.	Residual solvent (µg/g, by GC) Toluene	Below detection limit	Not more than 890	In house
25.	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
 21/03/2025	 21/03/2025	 21/03/2025
<b>Chhatrasinh Girase</b>	<b>Chakradhar Patil</b>	<b>Hemant Patel</b>
<b>Assistant – QA</b>	<b>Jr. Executive - QA</b>	<b>Dy. Manager – QA</b>