QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	: **Amioron 150** Amiodarone Intravenous infusion IP.		
Batch No.	: GA24E-32B	**Mfg. Date**	: 05/2024
Batch Size	: 12000 Ampoules	**Exp. Date**	: 04/2026
Sample Qty.	: 60 Ampoules	**Analytical Report No.:** AFP20240271	
Date of Receiving : 23/05/2024		**Date of Completion** : 06/06/2024	
Mfg. License No. : N-MB/18/201			

S. No.	Tests	Specifications	Observations
1.	Description	A Colourless to light yellowish colour liquid solution filled in 3 ml transparent glass ampoule.	A Colourless to light yellowish colour liquid solution filled in 3 ml transparent glass ampoule.
2.	Identification		
	A (By IR)	The IR spectrum of the sample should be concordant with the reference spectrum of Amiodarone HCL RS.	Complies
	B (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution should be corresponds to that in the chromatogram obtained with the reference solution.	Complies
3.	Uniformity of filled volume	Not less than nominal volume	Min: 3.0ml Max: 3.1 ml
4.	Average fill volume	Not less than 3 ml	3.02 ml
5.	Related substances		
	By TLC	Any other secondary spot is not more intense than the spot in the chromatogram obtained with reference solution (0.50%)	Complies
6.	Particulate Matter		
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule
7.	Sterility	Should be Sterile	Sterile
8.	Appearance of solution	Should be clear.	Clear
9.	Bacterial endotoxins	NMT 8.33 EU/mg	Less than 8.33 EU/mg
10.	Assay : Each ml contains:-		

Composition:	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Amiodarone Hydrochloride IP	50.0 mg	50.64 mg	101.28 %	95.0% to 105%

Remarks: In the opinion of the undersigned the sample submitted complies/does not complies with the prescribed standard/not standard of quality, as according to I.P. and IHS with respect to the above test only.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/ In-charge
Signature:- Date:-	Signature:- Date:-	Signature:- Date:-

Format No.: VH/SOP/QC-062/FT-01-00