

Title : Certificate of Analysis Finished Product

Product Name	Amioron 150 Injection	A.R. No.	NL/FP/24/001
Generic Name	Amiodarone Sterile Concentrate IP 3ml	Sampled qty.	45 Ampoules
Batch No.	A23541B	Sampled by	Arvind
Batch Size	25,000 Ampoule	Sampled on	01/04/2024
Mfg. Date	01/2024	Date of Testing	01/04/2024
Exp. Date	12/2025	Date of Release	16/04/2024

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.
2.	Identification (By I.R) (By HPLC)	A. Infrared absorption spectrophotometry compare the spectrum with that obtained with Amiodarone hydrochloride RS treated in the same manner or with the reference spectrum of Amiodarone. B. In the Assay, The principle peak in the chromatogram obtained with the test solution corresponding to that in the chromatogram obtained with the reference solution.	Complies Complies
3.	Nominal fill volume	NLT- 3.0 ml	3.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	3.1 ml
5.	Appearance of solution	The solution is not more intense the reference solution BYS4 or GYS4.	Complies
6.	pH	3.5 to 6.5	5.10
7.	Related Substance (By TLC)	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the working standard solution.	Complies
8.	Iodides	Measure the absorbance of test solution (a) and the reference solution at 420 nm using the solution (b) in the reference cell. The absorbance of the test solution is not more than the absorbance of reference solution (500 ppm).	Less than 500ppm
9.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/Ampoules NMT-600/Ampoules The solution should essentially free from particles of foreign matter that can be observed on visual inspection.	118/Ampoules 2/Ampoules Complies

Analysis by  Checked by  Approved by 

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10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT- 8.33 EU/mg of Amiodarone Hydrochloride.	Less than- 8.33 EU/mg of Amiodarone Hydrochloride.		
12.	Assay: Each 3ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Amiodarone Hydrochloride IP		150 mg	156.292 mg	104.19%	95.0% to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. ~~Complies/not complies~~ as per ~~IP/BP/USP/IHS~~.

Analysis by 	Checked by 	Approved by 
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