

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

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Certificate of Analysis Finished Product

Product Name	Amioron 150 Injection	A.R. No.	NL/FP/25/137
Generic Name	Amiodarone Sterile Concentrate IP 150mg/3ml	Sampled qty.	45 Ampoules
Batch No.	A25096B	Sampled by	Anuj Verma
Batch Size	30,000 Ampoules	Sampled on	25/07/2025
Mfg. Date	06/2025	Date of Testing	25/07/2025
Exp. Date	05/2027	Date of Release	09/08/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber 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	5.41
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).	Complies
9.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoules NMT 600/Ampoules The solution should essentially free from particles of foreign matter that can be observed on visual inspection.	65/Ampoules 1/Ampoules Complies

Analysis by

NAME: RAMANJEET SINGH

Checked by

NAME: NIKHIL SHARMA

Approved by

NAME: MRS. SWATI DHAWAN

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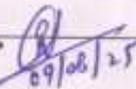
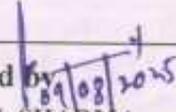
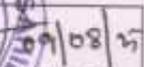
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10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT 8.33 EU/mg of Amiodarone Hydrochloride.	Less than 8.33 EU/mg of Amiodarone Hydrochloride.		
12.	Assay: (By HPLC) Each 3ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Amiodarone Hydrochloride IP		150 mg	148.241 mg	98.83%	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  NAME: RAMANJEET SINGH	Checked by  NAME: NIKHIL SHARMA	Approved by  NAME: MRS. SWATI DHANWAN
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