



Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	AMIORON Injection	A.R. No.	NL/FP/26/126
Generic Name	Amiodarone Sterile Concentrate IP 3ml	Sampled qty.	45 Ampoules
Batch No.	A26094A	Sampled by	Rakesh
Batch Size	49,650 Ampoules	Sampled on	09/07/2026
Mfg. Date	06/2026	Date of Testing	10/07/2026
Exp. Date	05/2028	Date of Release	25/07/2026

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	4.50
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 be essentially free from particles of foreign matter that can be observed on visual inspection.	240/Ampoules 13/Ampoules Complies Name : Mrs. Swati Dhawan Designation : QC HOD Qualification : M.Sc. Clinical Microbiology Registration No. : 580106039533 Approved by : NAME: MRS. SWATI DHAWAN

Analysis by

NAME: FIROJ KHAN

Checked by

NAME: SURJEET KAUR

Approved by

NAME: MRS. SWATI DHAWAN



Add Pace To Health

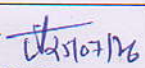
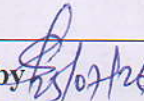
Pace Biotech

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

Title	:	Certificate of Analysis Finished Product	
Product Name	AMIORON Injection	A.R. No.	NL/FP/26/126
Generic Name	Amiodarone Sterile Concentrate IP 3ml	Sampled qty.	45 Ampoules
Batch No.	A26094A	Sampled by	Rakesh
Batch Size	49,650 Ampoules	Sampled on	09/07/2026
Mfg. Date	06/2026	Date of Testing	10/07/2026
Exp. Date	05/2028	Date of Release	25/07/2026

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	147.24448 mg	98.16%	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/HS.

Analysis by  NAME: FIROJ KHAN	Checked by  NAME: SURJEET KAUR	Name : Mrs. Swati Dhawan Designation : QC HOD Qualification : M.Sc. Clinical Pharmacy Registration No. : 5502050000000000 Approved by  NAME: MRS: SWATI DHAWAN Punjab Technical University, Jalandhar
---	---	--