

Pace

Add Pace To Health

Pace Biotech

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

Certificate of Analysis Finished Product

Title	:		
Product Name	Amioron 150 Injection	A.R. No.	NL/FP/24/528
Generic Name	Amiodarone Sterile Concentrate Injection IP 150mg/3ml	Sampled qty.	45 Ampoules
Batch No.	A24417A	Sampled by	Rakesh
Batch Size	15,000 Ampoule	Sampled on	24/02/2025
Mfg. Date	02/2025	Date of Testing	24/02/2025
Exp. Date	01/2027	Date of conditionally Release	07/03/2025

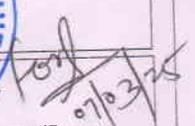
S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.
2.	Identification (By I.R.) (By HPLC)	A. Infrared absorption spectrophotometry compare the spectrum with that obtained with Amiodarone 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 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	5.31
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.	Under process
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).	Under process
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.	432/Ampoules 8/Ampoules Complies Quality Control Manager Approved by

Analysis by 
NAME: SUFIYAN ANSARI

Checked by 
NAME: SANDHYA

NAME: P. N. TRIPATHI





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10.	Sterility	No microbial growth should be observed.	Under process		
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	146.614 mg	97.74%	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: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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