

Pacé

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Pace Biotech

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

Title		: Certificate of Analysis Finished Product	
Product Name	Amioron 150 Injection	A.R. No.	NL/FP/24/355
Generic Name	Amiodarone Sterile Concentrate Injection IP 150mg/3ml	Sampled qty.	45 Ampoules
Batch No.	A24226A	Sampled by	Rakesh
Batch Size	20,000 Ampoule	Sampled on	14/10/2024
Mfg. Date	09/2024	Date of Testing	14/10/2024
Exp. Date	08/2026	Date of Conditionally Release	21/10/2024

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	5.97
7.	Related Substance (By TLC)		
	2-butyl-3-(4-hydroxy-3,5-di-Idobenzoyl) benzofuran	NMT- 1.6%	Not detected
	Any other secondary spot	NMT- 0.5%	Not detected
8.	Iodides	Not more than 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.	537/Ampoules 20/Ampoules Complies

Analysis by 

Checked by 

Approved by 



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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	152.884 mg	101.92%	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/AHS.

Analysis by  Checked by  Approved by 

