

Title

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Certificate of Analysis Finished Product

Product Name	DOBUTACAN Injection	A.R. No.	NL/FP/23/821
Generic Name	Dobutamine Injection USP 250mg/5ml	Sampled qty.	45 Ampoules
Batch No.	A23583A	Sampled by	Aakash
Batch Size	50,000 Ampoules	Sampled on	29/03/2024
Mfg. Date	02/2024	Date of Testing	29/03/2024
Exp. Date	01/2026	Date Of Release	13/04/2024

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	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the working standard solution.	Complies
3.	Nominal fill volume	NLT- 5ml	5.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	5.1 ml
5.	pH	2.5 to 5.5	3.84
6.	Particulate Matter	NMT-6000/Ampoule NMT-600/Ampoule	223/Ampoule 3/Ampoule
	(A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$		
	(B.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally.	Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT- 2.08 EU/mg of Dobutamine.	Less than- 2.08 EU/mg of Dobutamine.
9.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Dobutamine HCl I.P Eq. to Dobutamine	50 mg	47.98 mg	95.96%	90.0% to 110.0%

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 

