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Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	**DOBUTACAN** Injection	**A.R. No.**	NL/FP/23/699
Generic Name	Dobutamine Injection USP 250mg/5ml	**Sampled qty.**	45 Ampoules
Batch No.	A23481C	**Sampled by**	Vineet
Batch Size	12,865 Ampoules	**Sampled on**	08/02/2024
Mfg. Date	12/2023	**Date of Testing**	08/02/2024
Exp. Date	11/2025	**Date of Release**	23/02/2024

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	3.76
6.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	 NMT-6000/Ampoule NMT-600/Ampoule	 75.3/Ampoule 2.0/Ampoule
	(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 Hydrochloride I.P Eq. to Dobutamine	50 mg	50.99 mg	101.98%	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 M	**Checked by** S	**Approved by**

PACE BIOTECH (H.P.) Quality Control Manager