

# Pace

Add Pace To Health

# Pace Biotech

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

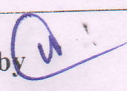
## Certificate of Analysis Finished Product


<b>Title</b>	:		
<b>Product Name</b>	DOBUTACAN Injection	<b>A.R. No.</b>	NL/FP/24/131
<b>Generic Name</b>	Dobutamine Injection USP 250mg/5ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	A24067A	<b>Sampled by</b>	Aakashdeep
<b>Batch Size</b>	50,000 Ampoules	<b>Sampled on</b>	31/05/2024
<b>Mfg. Date</b>	05/2024	<b>Date of Testing</b>	31/05/2024
<b>Exp. Date</b>	04/2026	<b>Date Of Release</b>	17/06/2024

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	3.01
6.	Particulate Matter (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$  (B.) Visual	NMT-6000/Ampoule NMT-600/Ampoule  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally.	265/Ampoule 1/Ampoule  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	49.31 mg	98.62%	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   
Manager

