

Pace

Add Pace To Health

Pace Biotech

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

Title

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Certificate of Analysis Finished Product

Product Name	NOR-ADR Injection	A.R. No.	NL/FP/25/109
Generic Name	Sterile Noradrenaline Concentrate IP 4mg/2ml	Sampled qty.	45 Ampoules
Batch No.	A25092A	Sampled by	Rakesh
Batch Size	2,00,000 Ampoules	Sampled on	29/06/2025
Mfg. Date	06/2025	Date of Testing	29/06/2025
Exp. Date	05/2027	Date of Release	14/07/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber colour glass ampoule.	A clear colourless solution filled in amber colour glass ampoule.
2.	Identification	Mix 0.5 ml with 10 ml of phthalate buffer pH 3.6, add 1ml of 0.05 M iodine, allow to stand for 5 minutes and add 2 ml of 0.1 M sodium thiosulphate ; not more than a very faint red colour is produced. Repeat the test using phosphate buffer pH 6.6 instead of phthalate buffer pH 3.6; a strong reddish violet colour is produced.	Complies
3.	Nominal fill volume	NLT 2ml	2.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml
5.	pH	3.0 to 4.6	3.83
6.	Particulate Matter (A.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visible particulate matter	NMT-6000/Ampoule NMT-600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	21/Ampoule 0/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 83.4 EU/mg of Noradrenaline.	Less than 83.4 EU/mg of Noradrenaline.
9.	Assay: Each ml contains		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Noradrenaline Bitartrate IP (Eq. to Noradrenaline 1mg)	2 mg	1.966 mg	98.30%	90.0 to 115.0%

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/BE/USP/IHS.

Analysis by NAME: SANDHYA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: SWATKDHAWAN
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