



American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Nor ADR 2ml Injection (Noradrenaline Concentrate IP Injection 2ml)		
Batch No.	25AR017	A.R. No.	AFP25008
Batch Size	150500 Ampoules	Sample Quantity	60 Nos
Mfg. Date	08/2025	Date of Testing	12/08/2025
Exp. Date	07/2027	Date of Release	10/09/2025
Reference Batch No	25AR017	MFG. Lic. No.	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless solution	Clear and colorless solution
2.	Identification	Mix 0.5 ml with 10 ml of phthalate buffer pH 3.6, add 1 ml 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.	pH	Between 3.0 to 4.6	3.84
4.	Extractable Volume	NLT 2.0 ml	2.0 ml
5.	Bacterial Endotoxins	NMT 83.4 Endotoxin unit per mg of noradrenaline	Less than 83.4 Endotoxin unit per mg of noradrenaline
6.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
7.	Sterility	Should be sterile	



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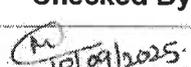
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			Sterile
8.	Assay: Each ml contains: Noradrenaline Bitartrate IP 2mg Eq.to Noradrenaline 1mg	1.90 mg to 2.1 mg (90.0 % to 110.0 %)	2.005 mg 100.25 %

Remark: The sample is complies as per ✓ IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 20/09/2025	 10/09/2025	 10/09/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

