



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 Injection (Noradrenaline Concentrate IP Injection 2ml)		
Batch No.	25AR050	A.R. No.	AFP250042
Batch Size	201000 Amp.	Sample Quantity	60 Nos
Mfg. Date	10/2025	Date of Testing	19/10/2025
Exp. Date	09/2027	Date of Release	05/11/2025
Reference Batch No	25AR050	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	3.91
4.	Extractable Volume	NLT 2 ml	2 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	Sterile



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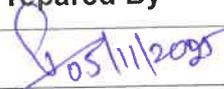
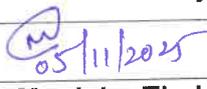
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8.	Assay: Each ml contains: Noradrenaline Bitartrate IP 2mg Eq.to Noradrenaline 1mg	1.90 mg to 2.1 mg (90.0 % to 110.0 %)	2.03 mg 101.5 %
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Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 05/11/2025	 05/11/2025	 05/11/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive QC	Head QC

