



## American Remedies Healthcare Pvt. Ltd.

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

### CERTIFICATE OF FINISHED PRODUCT ANALYSIS

<b>Product Name:</b>	ADR 1ml Injection (Adrenaline Bitartrate Injection IP 1mg/ml)		
<b>Batch No.</b>	25AR022	<b>A.R. No.</b>	AFP250027
<b>Batch Size</b>	300200 Ampoules	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	09/2025	<b>Date of Testing</b>	24/09/2025
<b>Exp. Date</b>	08/2027	<b>Date of Release</b>	11/10/2025
<b>Reference Batch No</b>	25AR022	<b>MFG. Lic. No.</b>	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	A clear, colourless or almost colourless solution	A clear, colourless solution
2.	Identification (A) BY HPLC  (B) By Chemically  (C) By Chemically	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponding to the peak in the chromatogram obtained with reference solution. B. To 1 ml add dropwise a 0.25 per cent w/v solution of ferric chloride until an emerald-green colour is produced. Add sodium bicarbonate solution gradually the solution changes first to blue and then to red. C. To 10 ml add 2 ml of disodium hydrogen phosphate solution and sufficient iodine solution to produce a brown colour. Add 0.1M sodium thiosulphate dropwise until excess iodine is removed a red colour is produced.	Complies
3.	pH	Between 2.8 to 3.6	3.48
4.	Extractable Volume	NLT 1.0 ml	1 ml
5.	Appearance of solution	It is not pinkish and does not contain a precipitate. If any yellow colour is observed it is not more intense than a reference solution prepared by diluting 0.4 ml of 0.7 M iodine to 100 ml with water, when viewed similarly.	Complies



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6.	<b>Noradrenaline</b>	NMT 1.0 %	Complies
7.	<b>Particulate Matter</b>	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
8.	<b>Bacterial Endotoxins</b>	NMT 357 EU/mg	Less than 357 EU/mg
9.	<b>Sterility</b>	Should be complies	Sterile
10.	<b>Assay:</b> Each ml contains <b>Adrenaline Bitartrate IP</b> eq to Adrenaline 1mg	(0.90 to 1.15 mg) 90.0 to 115.0 %	(1.01 mg) 101.15 %



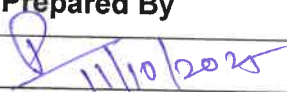
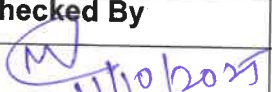

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Remark: The sample is complies as per IP /BP/ USP/IH specification. ✓

	Prepared By	Checked By	Approved By
Sign/Date	 11/10/2025	 11/10/2025	 11/10/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

