



## 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>	<b>ADR -1ml Injection (Adrenaline Bitartrate Injection IP 1mg/ml)</b>		
<b>Batch No.</b>	25AR040	<b>A.R. No.</b>	AFP250046
<b>Batch Size</b>	301000 Ampoules	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	10/2025	<b>Date of Testing</b>	01/11/2025
<b>Exp. Date</b>	09/2027	<b>Date of Release</b>	17/11/2025
<b>Reference Batch No</b>	25AR040	<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. the solution Should changes first to blue and then to red.  C. a red colour Should produced.	Complies
(D.	pH	Between 2.8 to 3.6	3.31
(E.	Extractable Volume	NLT 1.0 ml	1 ml
(F.	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
(G.	Noradrenaline	NMT 1.0 %	Complies
(H.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of	Complies



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		visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	
(I.)	<b>Bacterial Endotoxins</b>	NMT 357 EU/mg	Less than 357 EU/mg
(J.)	<b>Sterility</b>	Should be Sterile	Sterile
(K.)	<b>Assay:</b> Each ml contains Adrenaline Bitartrate IP eq to Adrenaline 1mg/ml	(0.90 to 1.15 mg) 90.0 to 115.0 %	(1.02 mg) 101.95 %

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

	<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Sign/Date</b>			
<b>Name</b>	<b>Prayash</b>	<b>Manisha Thakur</b>	<b>Bhupinder Navet</b>
<b>Designation</b>	<b>Officer QC</b>	<b>Executive-QC</b>	<b>Head-QC</b>



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