

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

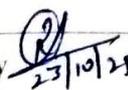
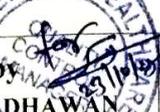
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour, (H.P) 173025

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	SOPRESSIN Injection	<b>A.R. No.</b>	ARN/FP/25/030
<b>Generic Name</b>	Vasopressin Injection IP 1ml	<b>Sampled qty.</b>	60 Ampoules
<b>Batch No.</b>	ARN2536A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	50,000 Ampoules	<b>Sampled on</b>	03/10/2025
<b>Mfg. Date</b>	09/2025	<b>Date of Testing</b>	03/10/2025
<b>Exp. Date</b>	08/2027	<b>Date of Release</b>	23/10/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.		
2.	Identification (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the working standard solution.	Complies		
3.	Nominal fill volume	NLT 1 ml	1.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml		
5.	pH	2.5 to 4.5	3.93		
6.	Particulate Matter (A.) Light Obscuration Particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$  (B.) Visual Particle	NMT 6000/Ampoule NMT 600/ Ampoule  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	7/Ampoule 1/Ampoule  Complies		
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Bacterial Endotoxins	NMT 17.0 EU/unit of Vasopressin.	Less than 17.0 EU/unit of Vasopressin.		
9.	Assay: (By HPLC) Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Vasopressin IP		20 units	21.167 units	105.84%	90.0% to 110.0%

**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/BP/USP/IHS.**

<b>Analysis by</b>  NAME: RAMANJEET SINGH	<b>Checked by</b>  NAME: SUFIYAN ANSARI	<b>Approved by</b>  NAME: MRS. SWATI DHAWAN
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