



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title	Certificate of Analysis Finished Product		
Product Name	SOPRESSIN 20U Injection	A.R. No.	ARN/FP/25/012
Generic Name	Vasopressin Injection IP 1ml	Sampled qty.	45 Ampoules
Batch No.	ARN2503A	Sampled by	Anuj Verma
Batch Size	64,400 Ampoules	Sampled on	26/08/2025
Mfg. Date	08/2025	Date of Testing	26/08/2025
Exp. Date	07/2027	Date of conditionally Release	05/09/2025

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	4.07
6.	Particulate Matter	NMT 6000/Ampoule NMT 600/ Ampoule	1100.00/Ampoule 136.67/Ampoule
	(A.) Light Obscuration Particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$		
	(B.) Visual Particle	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	Complies
7.	Sterility	No microbial growth should be observed.	10 days 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	19.58 units	97.90%	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/HIS~~.

Analysis by NAME: RAMANJEET SINGH	Checked by NAME: SUFIYAN ANSARI	Approved NAME: MRS. SWATI DHAWAN
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