

Title

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Certificate of Analysis Finished Product

Product Name	SOPRESSIN Injection	A.R. No.	NL/FP/24/216
Generic Name	Vasopressin Injection IP 1ml	Sampled qty.	45 Ampoules
Batch No.	A24148B	Sampled by	Aakash
Batch Size	5000 Ampoules	Sampled on	17/07/2024
Mfg. Date	07/2024	Date of Testing	17/07/2024
Exp. Date	06/2026	Date of Release	01/08/2024

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	3.96
6.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/Ampoule	30/Ampoule
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/ Ampoule	1/Ampoule
	(b.) Visual	The solution should essentially free from particles of foreign matter that can be observed on visual inspection.	Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT-17.0 EU/units of Vasopressin.	Less than-17.0 EU/units of Vasopressin.
9.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Vasopressin IP	20 units	20.24 units	101.20%	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.

Analysis by

Checked by

