



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

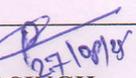
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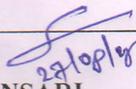
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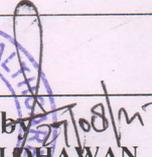
Certificate of Analysis Finished Product

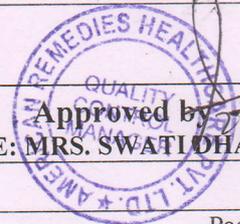
Product Name	Dopacan Injection	A.R. No.	ARN/FP/25/002
Generic Name	Dopamine Hydrochloride Injection IP 5ml	Sampled qty.	45 Ampoules
Batch No.	ARN2513A	Sampled by	Anuj verma
Batch Size	50,000 Ampoules	Sampled on	12/08/2025
Mfg. Date	08/2025	Date of Testing	12/08/2025
Exp. Date	07/2027	Date of Release	27/08/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless liquid filled in amber colour glass ampoule.	A clear colourless liquid filled in amber colour glass ampoule.
2.	Identification By IR	A. Compare the spectrum with that obtained with dopamine hydrochloride IPRS treated in the same manner or with the reference spectrum of dopamine hydrochloride.	Complies
	By Chemically	B. To a volume containing 10 mg of Dopamine Hydrochloride, add 0.1 ml of a 10.5 per cent w/v solution of iron (III) chloride hexahydrate. An intense green colour is produced.	Complies
3.	Nominal fill volume	NLT 5ml	5.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	5.1 ml
5.	pH	3.0 to 4.5	4.32
6.	5-Hydroxymethylflurfural (HPLC)	NMT 0.05%	Not detected
7.	Related Substances (By HPLC)		
	Area of any secondary peak	NMT 2.5%	0.07%
	Total Impurities	NMT 2.0%	0.11%
8.	Particulate Matter (A.) Light Obscuration Particle Count Test (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.	105/Ampoule 2/Ampoule Complies

Analysis by 
NAME: RAMANJEET SINGH

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: MRS. SWATI CHAWAN





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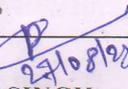
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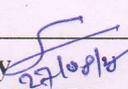
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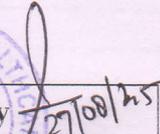
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9.	Sterility	No microbial growth should be observed.	Complies		
10.	Bacterial Endotoxins	NMT 26.67 EU/ml of Dopamine Hydrochloride in water for injection.	Less than 26.67 EU/ml of Dopamine Hydrochloride in water for injection.		
11.	Assay: Each ml contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Dopamine Hydrochloride IP		40 mg	41.17 mg	102.93%	95.0% to 105.0%

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 by 
NAME: MRS. SWATI DHAWAN

