



**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**  
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

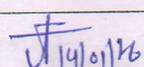
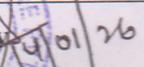
**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	DROTACAN Injection	<b>A.R. No.</b>	ARN/FP/25/082
<b>Generic Name</b>	Drotaverine Hydrochloride Injection 2ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	ARN2582A	<b>Sampled by</b>	Rakesh
<b>Batch Size</b>	10,3000 Ampoules	<b>Sampled on</b>	30/12/2025
<b>Mfg. Date</b>	12/2025	<b>Date of Testing</b>	31/12/2025
<b>Exp. Date</b>	11/2027	<b>Date of Release</b>	14/01/2026

S. No.	Tests	Specifications	Observations
1.	Description	A yellowish colour solution filled in amber glass ampoule.	A yellowish colour solution filled in amber glass ampoule.
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Nominal fill volume	NLT- 2ml	2.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml
5.	pH	3.5 to 5.0	4.44
6.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/Ampoule NMT-600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	19/Ampoule 0/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 4.37 EU/mg of Drotaverine Hydrochloride.	Less than 4.37 EU/mg of Drotaverine Hydrochloride.
9.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Drotaverine Hydrochloride IP	20 mg	20.00819 mg	100.04%	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  NAME: FIROJ KHAN	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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