

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

Title**:****Certificate of Analysis Finished Product**

Product Name	DROTACAN Injection	A.R. No.	ARN/FP/26/013
Generic Name	Drotaverine Hydrochloride Injection 2ml	Sampled qty.	45 Ampoules
Batch No.	ARN2618A	Sampled by	Rakesh
Batch Size	1,00,000 Ampoules	Sampled on	19/05/2026
Mfg. Date	05/2026	Date of Testing	20/05/2026
Exp. Date	04/2028	Date of Release	04/06/2026

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	4.36
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.	38/Ampoule 1/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	19.96317 mg	99.82%	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: SHAHRUKH KHAN

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS.SWATI DHAWAN