

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

Product Name	Dopacan Injection	A.R. No.	NL/FP/24/486
Generic Name	Dopamine Hydrochloride Injection IP 5ml	Sampled qty.	45 Ampoules
Batch No.	A24369D	Sampled by	Boby Kumar
Batch Size	25,100 Ampoules	Sampled on	20/01/2025
Mfg. Date	12/2024	Date of Testing	20/01/2025
Exp. Date	11/2026	Date of Release	04/02/2025

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. On the residue, determine by infrared absorption. Compare the spectrum with that obtained with dopamine Hcl RS treated in the same manner or with the reference spectrum of dopamine.	Complies
	By Chemically	B. 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	3.94
6.	5-Hydroxymethylflurfural	NMT-0.05%	Not detected
7.	Related Substances (By HPLC)		
	Single Impurity	NMT-2.5%	Not detected
	Not more than one such peak	NMT-2.0%	Not detected
8.	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.	779/Ampoule 8/Ampoule Complies
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT- 26.67 EU/ml of Dopamine Hydrochloride.	Less than- 26.67 EU/ml of Dopamine Hydrochloride.
11.	Assay: Each ml contains:		

Analysis by
NAME: SUFIYAN ANSARI

Checked by
NAME: SANDHYA

Approved by
NAME: P. N. TRIPATHI



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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Dopamine Hydrochloride I.P	40 mg	41.05 mg	102.63%	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/IHS.



Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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5. pH	NMT 5.0	Not detected
6. 5-Hydroxytryptamine	NMT 1000 µg/ml	Not detected
7. Related Substances (By HPLC)	NMT 1.0%	Not detected
8. Single Impurity	NMT 1.0%	Not detected
9. Not more than one such impurity	NMT 1.0%	Not detected
10. Particulate Matter (a) Sub-visible particle count (1) Particles >10µm (2) Particles >25µm (b) Visual	NMT 6000/Ampoule NMT 60/Ampoule The solution should be essentially free from extraneous visible undissolved particles, other than gas bubbles, when inspected.	279 Ampoules 6 Ampoules Clear
11. Sterility	No microbial growth should be observed.	Pass
12. Bacterial Endotoxins	NMT 26.67 EU/ml of Dopamine Hydrochloride.	Less than 26.67 EU/ml of Dopamine Hydrochloride.
13. Assay	Each ml contains	

Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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