



HANUCHEM LABORATORIES

Parwanoo (H.P)

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CERTIFICATE OF ANALYSIS

Product Name:	I-Chill [®] eye drops (Chlorpheniramine Maleate, Naphazoline Hydrochloride, Phenylephrine HCl, Menthol & Camphor Ophthalmic Solution)		
Batch No.	HLF4086B	A. R. No.	ED/FG/240226
Mfg. Date	May-2024	Exp. Date	Apr-2026
Batch Size	20,000 Vial	Analysis Date	20/06/2024
Sample Quantity	60 Vials	STP No.	In house

Sr. No.	Tests	Results	Specification Limit
1	Description	A Clear colourless solution filled in a white plastic vial.	A Clear colourless solution filled in a white plastic vial.
2	Identification	Complies	Positive for Potassium iodide, calcium chloride and Sodium chloride.
3	pH	5.71	5.0 to 6.5
4	Average fill volume	10.1 ml	The average net volume of 20 vials not less than 10.0 ml
5	Uniformity of fill volume	Min: 100.00% Max: 100.99%	The net volume of any single container is not less than 91.0 % and not more than 109.0 % of the net average fill.
6	Assay Composition: Naphazoline Hydrochloride USP---0.05% w/v Chlorpheniramine Maleate IP---0.1% w/v Phenylephrine HCl IP----0.12% w/v Camphor USP----0.01% w/v Menthol IP---0.005%w/v Benzalkonium chloride solution IP----0.02% v/v	0.0549%w/v (109.8%w/v) 0.103% (w/v) (102.6%) 0.121%w/v (101.0%) 0.0102% w/v (102.0%) 0.0052% w/v (104.0%) 0.0201%w/v (100.5%)	0.045 % w/v to 0.055 % w/v (90.0 to 110.0 %) 0.090%v/v to 0.110 % v/v (90.0 to 110.0 %) 0.108%w/v to 0.132% w/v (90.0 to 110.0 %) 0.009%w/v to 0.011% w/v (90.0 to 110.0 %) 0.0045%w/v to 0.0055% w/v (90.0 to 110.0 %) 0.018%w/v to 0.022% w/v (90.0 to 110.0 %)
7	Sterility	Complies	Should be sterile

Remarks: The above sample Complies/~~Does not comply~~ as per Inhouse specification.

	Prepared By	Checked By	Approved By
Name	Niraj Yadav	Rajan Mishra	Sanjeev Kumar
Designation	QC Officer	Officer	Quality Control Head
Sign/Date	Niraj 05/07/24	Rajan 05/07/24	Sanjeev 05/07/24