SUNVET HEALTHCARE

SUNVET HEALTHCARE
VILLAGE- SHAMBHUWALA, NAHAN, PAONTA ROAD,
DISTT- SIRMOUR (HP) - 173001

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Product Name	**NALOPID INJECTION**		
Generic Name	Naloxone Hydrochloride Injection IP	**A.R. No.**	INJ/25938/2025
Batch No.	SAI-25938	**Batch Size**	67200 Ampoules
Mfg. Date	02/2026	**Exp. Date**	01/2028
Sample Qty.	100 Ampoules	**Reference Protocol**	IP & IH
Date of Testing	31.03.2026	**Date of Release**	07.04.2026

Test	Specification	Result
Description	A clear colourless solution filled in amber glass ampoules.	A clear colourless solution filled in amber glass ampoules.
Identification A. By HPLC	A. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.	A. Complies
B. By TLC	B. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	B. Complies
Nominal Volume (ml)	NLT 1.0 ml	1.0 ml
Extractable Volume (ml)	NLT nominal volume	**1.** 1.1,**2.** 1.1,**3.** 1.1, **4.** 1.1,**5.** 1.1. Average: 1.1 ml
Particulate matter	Should be free from visible particles.	No visible particle is seen with naked eyes.
pH	3.0 to 4.5	3.889
Bacterial Endotoxins	NMT 70 EU/mL	Less Than 70 EU/mL
Sterility	Should be Sterile	Under Observation
Related Substances: BY TLC	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution (0.5 per cent).	Complies

Prepared By		Checked By		Approved By	
Name	Manju	**Name**	Sudeepsingh	**Name**	RAMBIR
Sign./Date	07.04.2026	**Sign./Date**	07.04.2026	**Sign./Date**	07.04.2026
Designation	Q.C Offic	**Designation**	Asstmgr QC	**Designation**	Q.C Manager

Format No. : SH/F09/QCD/056/05

RAMBIR SINGH
B.Sc.
Approved Compelent Technical Person
(Chemical,Instrument and Microbiology)
Enrolment No. DFO/Drugs/285/22

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Assay Naloxone Hydrchloride Dihydrate IP Eq. to anhydrous Naloxone Hydrchloride 400 mcg	380.0 mcg to 420.0 mcg (95.0 % to 105.0 %)	400.0918 mcg (100.02 %)

Remarks: In the opinion of the undersigned the sample referred to above is of standard quality as defined in the Drug & Cosmetic Act rules there under for the reason that it Complies/~~Does not complies~~ with IP/~~BP/USP~~/IH Specification.

Prepared By		Checked By		Approved By	
Name	Megha	**Name**	Swjeet Singh	**Name**	RAMBIR
Sign./Date	07.04.2026	**Sign./Date**	07-04-26	**Sign./Date**	Rambir 07.04.2026
Designation	QC officer	**Designation**	Asstt. Mgr.	**Designation**	Q.C. Manager

Format No. : SH/F09/QCD/056/05

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