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 Injection IP	**A.R. No.**	INJ/26504B/2026
Batch No.	SAI-26504B	**Batch Size**	100000 Ampoules
Mfg. Date	08/2026	**Exp. Date**	07/2028
Sample Qty.	100 Ampoules	**Reference Protocol**	IP & IH
Date of Testing	17.10.2026	**Date of Release**	31.10.2026

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.** 1.02, **2.** 1.04, **3.** 1.04, **4.** 1.03, **5.** 1.04. Average: 1.03 ml
Particulate matter	Should be free from visible particles.	No visible particle is seen with naked eyes.
pH	3.0 to 4.5	3.36
Bacterial Endotoxins	NMT 70 EU/ml	Less Than 70 EU/ml
Sterility	Should be Sterile	Complies
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	Mukta	**Name**	Sanjeet Singh	**Name**	RAMBIR
Sign./Date	Mukta 31.10.2026	**Sign./Date**	31-10-26	**Sign./Date**	Rambir 31.10.2026
Designation	Q.C. officer	**Designation**	Assistant Manager	**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/285/2291

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Assay Naloxone Hydrochloride Dihydrate IP Eq. to anhydrous Naloxone Hydrochloride 400 mcg	380.0 mcg to 420.0 mcg (95.0 % to 105.0 %)	411.99 mcg (103.00 %)

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	Mukta	**Name**	Sujeet Singh	**Name**	RAMBIR
Sign./Date	Mukta 31.10.2026	**Sign./Date**	31-10-2026	**Sign./Date**	Rambir 31.10.2026
Designation	Q.C. officer	**Designation**	Asstt. QC	**Designation**	Q.C. Manager

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

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