



Navkar Lifesciences

Village- Kishanpura, Tehsil- Nalagarh, Distt. Solan, Baddi. (H.P.)

Mfg. Lic. No. L/19/232/MNB&L/19/2233/MB

Quality Control Department
(FINISH PRODUCT REPORT)

Product Name	Acido Ascorbico Inyectable (Ascorbic Acid Injection B.P.500mg/5ml)	Report No.	AHC/18/12/24/02
Mfg. By	Navkar Lifesciences	Supplied to	DISFASUR
Batch No.	L40129	Sampled Qty.	50 Ampoules
Batch Size	51000 Ampoules	Date of Receipt	25/11/2024
Mfg. Date	11/2024	Date of Analysis	25/11/2024
Exp. Date	10/2026	Date of Release	09/12/2024

Result of Analysis

S. No	Tests	Specification	Observations
1.	Description	A clear colourless liquid filled in 5 ml amber coloured glass ampoule.	A clear colourless liquid filled in 5 ml amber coloured glass ampoule.
2.	Identification (By TLC)	The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that in the chromatogram obtained with solution (2)	Complies
3.	Average net filled volume	NLT-5.0 ml	5.4 ml
4.	Extractable Volume	+15 % of Nominal volume	+ 5.0%
5.	pH	5.0 to 6.5	6.27
6.	Oxalic Acid	Not more than 0.3 %	Complies
7.	Particulate Matter A)Visible particle B)Sub Visible particle	Free from any type of visible particles NMT 6000 particles / Ampoules for $\geq 10\mu\text{m}$ NMT 600 particles / Ampoules for $\geq 25\mu\text{m}$	Solution is free from any type of visible particles 2123 particles/ Ampoule 21 particles/ Ampoule
8.	Sterility Test	Should be sterile	Complies
9.	Assay Each 5 ml contains: Ascorbic Acid BP	Claim 500 mg Limit 475.0 mg to 525.0 mg	Result 519.29 mg(103.86 %)

Remarks: In the opinion of undersigned, the sample referred to above is of Standard Quality as defined in the act and the rules made their under for the reason that it complies / does not comply with B.P and In-House specification.

Designation	OFFICER-QC	EXECUTIVE-QC	MANAGER-QC
Name	Sandeep	Ahmed	Ram
Sign /Date	09/12/2024	09/12/2024	09/12/2024