



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

Quality Control Department
(FINISH PRODUCT REPORT)

Product Name	Acido Ascorbico Inyectable (Ascorbic Acid Injection BP 500 mg/5ml)	Report No.	AHI/15/07/23/A2
Mfg. By.	NAV KAR LIFESCINECES	Supplied to.	DISFASUR
Batch No.	G30002	Sample Qty.	50 Ampoules
Batch Size	56000 Ampoules	Date of Receipt	15/07/2023
Mfg. Date	07/2023	Date of Analysis	15/07/2023
Exp. Date	06/2025	Release Date	29/07/2023

Certificate of Analysis

S.No	Tests	Results	Limits	
1.	Description	A clear colourless liquid filled in 5.0 ml Amber coloured glass ampoule.	A clear colourless liquid filled in 5.0 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	5.02 ml	
4.	pH	5.5 to 6.5	6.08	
5.	Oxalic Acid	NMT-0.3%	Complies	
6.	Identification	Compleis as per specification	Complies	
7.	Extractable volume	+15% of Nominal volume	+6.55%	
8.	Particular matter* A) Visual particles B) Sub visual particles	Free from any type of visible particles NMT 6000 particles/vial for $\geq 10\mu\text{m}$ NMT 600 particles/vial for $\geq 25\mu\text{m}$	Solution is free from any type of visible particles. 2224.0 particles/container 20.7 particles/container	
9.	Sterility test	To comply as per specification	Complies	
10.	Assay:* Each 5.0 ml Containt- Ascorbic Acid IP	Claim 500 mg	Limit 475.0mg to 525.0 mg	Result 497.1365mg(99.42%w/v)

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 is / complies / does not complies with in B.P. & In - house Specification.

* Refer to Report No. OALB230729070.

Designation	Q.C Officer	Q.C Executive	Q.C Manager
Name	HASNIYESH KARI	SUSHEESHA KARI	BHASKAR SHINAGARG
Sing/ Date			