NAVKAR LIFESCINECES
Village- Kishanpura, Tehsil- Nalagarh, Distt. Solan, Baddi. (H.P.)
Quality Control Department
(FINISH PRODUCT REPORT)

Product Name	Ceftriaxona Inyectable (Ceftriaxone For Injection USP 1000 mg)	**Report No.**	AHI/01/08/23/A
Manufactured by	Navkar Lifesciences	**Supplied to.**	DISFASUR
Batch No.	G30003	**Sampled Qty.**	50 vial.
Batch Size	10200 Vials	**Date of Receipt**	18/07/2023
Mfg. Date	07/2023	**Date of Analysis**	18/07/2023
Exp. Date	06/2025	**Date of Release**	01/08/2023

Result of Analysis

S.No	Tests	Results	Limits
1.	Description	A white powder filled in clear transparent 10 ml glass vial sealed with blue coloured F/O seal.	A white powder filled in clear transparent 10 ml glass vial sealed with blue coloured F/O seal.
2.	Average Filled Weight	1200 mg ± 5 %	1196.86 mg
3.	pH	6.0 to 8.0	7.18
4.	Identification A). By IR; B). By HPLC:	The IR Absorption Spectrum obtained of the Concordant with the working standard of Ceftriaxone Sodium. The chromatogram of the assay preparation obtained as directed in the assay exhibits a major peak for ceftriaxone the retention time of which correspond to that exhibited in the chromatogram of the preparation obtained as directed in the assay.	Complies Complies
5.	Uniformity of Filled Weight	± 10% of Net Filled Weight	-1.57 % to + 2.17 %
6.	Particulate Matter	The reconstituted solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies
7	Constituted solution	When reconstituted with SWFI the materials should dissolve an undissolved matter	Complies
8	Completeness and clarity of solution	The constituted solution not significantly less clear than an equal volume of the diluents or of water for injection content in a similar vessel and examined similarly.	Complies
9	Crystallinity	Meets the requirement.	Complies
10	Appearance of solution	A 1.2 % w/v solution in carbon free water is clear and not more intensely coloured than reference solution BYS5 or YS5.	Complies
11	Related substances (ByHP LC): A-Deacetylcefotaxime lactone B-7-Aminocecephalosporanic acid C-Ceftriaxone triazine analog D- Celtriaxone benzothiazolyl oxime	 NMT-0.5 % Not Reported NMT I.O% NMT 0,2%	 0.15 % Not Reported 0.21 % 0.03 %

Designation	Q.C. Officer	Q.C. Executive	Manager Q.C
Name	HARIS PANGARI	SUSHIL THAKARI	BHASKAR SHINAGARG
Sign./Date	18/8/23	18-8-23	Bhaskar 18-08-2023

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	E-Deacyl Ceftriaxone F-Cefriaxone-3-ene isomer C-Ceftriaxone E-isomer H-Individual Impurity I-Total Impurity	NMT-1,0% NMT-0.3% NMT-1.0% NMTO.2% NMT-5.0%	0. 15 % 0,09 % 0.28 % 0.06 % 1.37 %
12	Sterility Test	Should be sterile	Complies
13	Bacterial Endotoxins	Not more than 0.20 USP Endotoxins units per mg of Ceftriaxone.	Complies
14	Water	Between 8.0 % and 11.0 %	8.23 % w/w
15	Assay* Each vial Contains- Ceftriaxone Sodium USP (sterile) eq. to Ceftriaxone	Claim Limits 1000 mg 900mg to 1100 mg	Result 992.6 mg (99.26 % w/w)

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 complies with USP Specification.
***Refer to Report No.** OALB230729003.

Designation	Q.C. Officer	Q.C. Executive	Manager Q.C
Name	NASIB ANSARI	SUSHIL TIWARI	BHASKAR SHANAGARG
Sign./Date		5-8-2023	5-8-2023