



CAPTAB BIOTEC UNIT-II
PLOT No. 125, EPIP ROAD, MAUJA JHARMAJRI, BADDI, DIST. - SOLAN (HP)

CERTIFICATE OF ANALYSIS-FINISHED PRODUCTS

Product Name	AONE 500MG (Ceftriaxone Injection I.P.)		
B. No.	DC21004	A. R. No.:	CTBFPDCCN0422003
Mfg. date:	04/2022	Date of received:	04/04/2022
Exp. date:	03/2024	Date of Analysis:	04/04/2022
Batch Size:	5,500 Vials	Date of completion:	18/04/2022
Sample quantity:	42 Vials	Release date	18/04/2022

S. No.	TESTS	SPECIFICATION	RESULT
1.	Description	A white or almost white powder filled in clear glass vial closed with rubber plug and sealed with flip-off aluminium cap.	A white powder filled in clear glass vial closed with rubber plug and sealed with flip-off aluminium cap.
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Average filled weight	600 mg; \pm 5%	600.7 mg
4.	Uniformity of weight	Not more than two of the individual weights deviate from the average weight by more than 10% and none deviates by more than twice that percentage.	Complies
5.	Appearance of solution	A 1.20 % w/v solution in carbon dioxide free water is clear and not more intensely coloured than reference solution .	Solution is clear and not more intensely coloured than reference solution YS5.
6.	Particulate matter	The reconstituted solution should be free from foreign particles on visual inspection.	Complies
7.	pH of reconstituted solution.	Between 6.0 and 8.0	6.93
8.	Water	Not more than 11.0% w/w	8.26% w/w
9.	Particulate Contamination	Not more than 6000 Particles/container of $\geq 10\mu$.	283 Particles/container
10.	Sterility	Not more than 600 Particles/container of $\geq 25\mu$. Should comply the test for sterility.	74 Particles/container Complies
11.	Bacterial endotoxins	Not more than 0.20 Endotoxin unit/mg	Complies
12.	Assay: Each vial contains Ceftriaxone sodium (Sterile) IP Eq. to Anhydrous Ceftriaxone 500 mg	450.00 mg to 575.00 mg (90.00 % to 115.00%)	502.41 mg (100.48%)

Remark: The sample complies/does not comply with I.H./I.P./U.S.P Specifications with respect to above tests.

Analyzed By Sign/Date	Checked By Sign/Date	Approved By Sign/Date
 18/04/2022	 18/04/2022	 18/04/2022