

TEST RESULTS

Date / Period of Performance of test 03/07/2024 to 19/07/2024.

Reference to protocol :- I.P-2022.

Description :- White powder filled in transparent glass vials.

Identification (A) (by HPLC) :- Complies.

(B) :- Complies.

Sterility :- Complies with the test for sterility

LIMIT

		Lower	Upper
Bacterial endotoxins	:- Less than 0.20EU/mg of cefotaxime	-	0.20EU/mg. of cefotaxime

pH	:- 5.51	4.5	6.5
(of the 10%w/v reconstituted solution in water for injection)			

Average Net weight :- 1.1091gm.

Uniformity of weight :- Within limit.

Water (by KF)	:- 1.67%w/w	-	3.0%w/w.
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Related Substances (by HPLC) :- Complies.

Clarity of solution (Of reconstituted solution) :- Complies.

Particulate matter (Of reconstituted solution) :- Complies.

Assay (HPLC) :- Each vial contains:-

	Obtained	Claim	Lower	LIMIT Upper	Method
Contents of Cefotaxime Sodium eq. to Cefotaxime	:- 994.24mg	1000.0mg,	900.0mg	1150.0mg.	IP.

NOTE:- SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

