

TEST RESULTS

Date / Period of Performance of test 08/06/2024 to 22/06/2024.

Reference to protocol :- I.P-2022.

Description :- White powder filled in transparent glass vials.

Identification (A) (by I.R) :- Complies.

(B) (by HPLC) :- Complies.

(C) :- Complies.

Apearance of solution :- Complies.

Of reconstitution solution

		LIMIT	
		Lower	Upper
Specific optical rotation	:- +249.72°	+240°	+290°
pH	:- 9.02	8.0	10.0
Clarity of solution (After reconstitution)	:- Complies		
N,N-Dimethylaniline (by GC)	:- Not detected		NMT 20ppm.
Water (by KF)	:- 1.9998%w/w		4.0 %w/w
Bacterial endotoxins	:- Less than 0.25EU/mg		0.25EU/mg.
Sterility	:- Complies with the test for Sterility.		
Particulate Matter (After reconstitution)	:- Complies		
Sodium chloride	:- 1.0135%w/w		NMT 2.0%w/w
Average fill	:- 269.3mg		
Heavy metals	:- Less than 20.0ppm		NMT 20ppm
Uniformity of weight	:- Within limits.		
Assay (by HPLC)	:- Each vial contains:-		

		LIMIT			
Contents of	Obtained	Claim	Lower	Upper	Method
Amoxicillin Sodium					
Calculated as Amoxicillin	:- 246.21mg	250.0mg.	225.0mg.	300.0mg.	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 per IP.

