

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.
 Appearance of solution :- Complies.
 Of reconstitution solution

| | | LIMIT | |
|---|--|-------|-------------|
| | | Lower | Upper |
| Specific optical rotation | :- +250.21° | +240° | +290° |
| pH | :- 9.15 | 8.0 | 10.0 |
| Clarity of solution (After reconstitution) | :- Complies | | |
| N,N-Dimethylaniline (by GC) | :- Not detected | | NMT 20ppm. |
| Water (by KF) | :- 2.0069%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 | :- 1.0198%w/w | | NMT 2.0%w/w |
| Average fill | :- 547.2mg | | |
| Heavy metals | :- Less than 20.0ppm | | NMT 20ppm |
| Uniformity of weight | :- Within limits. | | |
| Assay (by HPLC) | :- Each vial contains:- | | |

| | | LIMIT | | | | |
|-----------------------------------|-------------|----------|----------|----------|-------|--------|
| | | Obtained | Claim | Lower | Upper | Method |
| Contents of Amoxycillin Sodium | | | | | | |
| Calculated as Amoxycillin | :- 497.21mg | 500.0mg. | 450.0mg. | 600.0mg. | | 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 per IP.