

**CERTIFICATE OF ANALYSIS**

| | | | | |
|-----------------|-------------------------------------------------|---------------------|---|------------|
| Product | : Ampicillin Anhydrous BP2018/EP9.0 (Compacted) | Date | : | 12/01/2019 |
| Lot No. | : P/AMP-0001/19 | Date of Mfg. | : | 01/2019 |
| AR No. | : FP00870119 | Date of Exp. | : | 12/2021 |
| Lot size | : 500 kg | | | |

| TEST | RESULT | SPECIFICATION |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Appearance | : White granules | : White or almost white granules |
| Solubility | : Sparingly soluble in water, practically insoluble in acetone, in ethanol (96 %) and in fatty oils. It dissolves in dilute solutions of acids and of alkali hydroxides. | |
| Identification | | |
| A. By IR | : IR spectra of sample is similar to that of working standard | : IR spectra of the sample should be similar to that of working standard. |
| D. Water test | : complies | : Not more than 2.0%w/w |
| Appearance of solution | : complies | : The solutions are not more opalescent than reference suspension II |
| pH | : 4.66 | : 3.5 to 5.5 |
| Specific Optical Rotation | : +295.5° | : +280° to +305° |
| Related Substances | : 0.21% | : Any impurity not more than 1.0 % |
| N, N-Dimethylaniline | : Not tested* | : Not more than 20 ppm |
| Water | : 0.66% w/w | : Not more than 2.0%w/w |
| Sulphated ash | : 0.10% w/w | : Not more than 0.5%w/w |
| Assay | : 99.14% w/w | : 96.0% to 102.0% w/w of $C_{16}H_{19}N_3O_4S$ (On anhydrous basis) |

Additional Tests

| | | |
|-------------------|-------------|---------------------------|
| Tapped density | : 0.87gm/ml | : Not less than 0.80gm/ml |
| Particle size | | |
| Pass through 20# | : 92.1% | : Not less than 90%w/w |
| Pass through 100# | : 34.3% | : Not more than 35%w/w |

REMARK : The product complies with BP2018/EP9.0

Note *1- N, N-Dimethylaniline is not used in manufacturing process
2- Material shall comply with current editions of IP, BP and USP if tested, wherever applicable.

Sign with date

Designation

Akmal
14/01/19
Analysed by
(QC- Chemist)

[Signature]
14/01/19
Checked by
(QC- In-charge)

[Signature]
14/01/19
Approved by
(QA- Head)