



**CERTIFICATE OF ANALYSIS**

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

| <b>TEST</b>               | <b>RESULT</b>  | <b>SPECIFICATION</b>   |
|---------------------------|--|--|
| 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. | : 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 <sub>16</sub> H <sub>19</sub> N <sub>3</sub> O <sub>4</sub> S (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

*Ajmal*  
14/01/19

*[Signature]*  
14/01/19

*[Signature]*  
14/01/19

Designation

Analysed by  
(QC- Chemist)

Checked by  
(QC- In-charge)

Approved by  
(QA- Head)