
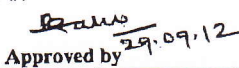


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| QUALITY ASSURANCE DEPARTMENT | | |
|---|---|--|
| CERTIFICATE OF ANALYSIS | | |
| Product Name : Cefazolin Sodium EP (Sterile) | | |
| Batch No. : CZSU120074 | | |
| Mfg. Date : Aug 2012 | | Date of Release : 29/09/2012 |
| Retest Date : Jul 2015 | | Quantity : 200.00 kg |
| Storage Condition: Store at a temperature not exceeding 25°C, in a sterilized tamper evident aluminum container, protected from light, and closed with sterilized rubber stopper, finally sealed with sterilized aluminum seal. | | |
| Tests | Observations | EP Specifications |
| 1. Description | White powder, very hygroscopic | A white or almost white powder, very hygroscopic. |
| 2. Solubility | Freely soluble in water. | Freely soluble in water. |
| 3. Identification | IR spectrum matches with that of standard Gives characteristic reaction for sodium | IR spectrum of test should match with that of standard Should give characteristic reaction for sodium |
| 4. Appearance of solution | Solution S is clear | Solution S should be clear |
| Absorbance at 430nm | 0.015 | The absorbance of solution S should be not more than 0.15 |
| 5. pH | 5.0 | Between 4.0 and 6.0 (10.0% w/v aq. solution) |
| 6. Specific optical rotation | -18.0 ° | Between -15.0° and -24.0°, on anhydrous basis |
| 7. Absorbance | Complies | The solution should show maximum at 272nm |
| Specific absorbance at 272nm | 296 | Between 260 and 300, on anhydrous basis |
| 8. Related substances (by HPLC) | | |
| EP Impurity A | Not detected | Not more than 1.0% w/w, on as is basis |
| EP Impurity B | 0.02% | Not more than 1.0% w/w, on as is basis |
| EP Impurity C | Not detected | Not more than 1.0% w/w, on as is basis |
| EP Impurity D | Not detected | Not more than 1.0% w/w, on as is basis |
| EP Impurity E | 0.25% | Not more than 1.0% w/w, on as is basis |
| EP Impurity G | 0.06% | Not more than 1.0% w/w, on as is basis |
| EP Impurity H | Not detected | Not more than 1.0% w/w, on as is basis |
| EP Impurity I | 0.13% | Not more than 1.0% w/w, on as is basis |
| EP Impurity L | 0.01% | Not more than 1.0% w/w, on as is basis |
| Highest unknown impurity | 0.06% | Not more than 0.10% w/w, on as is basis |
| Total impurities | 0.53% | Not more than 3.5% w/w, on as is basis |
| 9. Water | 0.9 % | Not more than 6.0% w/w, by KF method |
| 10. Sterility | Sterile | Should be sterile |
| 11. Bacterial endotoxins | < 0.010 EU/mg | Less than 0.15 IU/mg of Cefazolin |
| 12. Particulate matter | | |
| Visual test | Free from visual particles | Should be essentially free from any type of visual particles |
| (>=10 µm) | 53 | Not more than 1000/g |
| (>=25 µm) | 16 | Not more than 100/g |
| 13. Assay | 97.9 % | Between 95.0% and 102.0% w/w, as Cefazolin sodium, on anhydrous basis, by HPLC |
| Additional tests : | | |
| 14. Residual solvents (by GC-HS) | | |
| Acetone | 64 ppm | Not more than 5000 ppm |
| Triethyl amine | 221 ppm | Not more than 320 ppm |
| 15. Boron | <1.0 ppm | Not more than 5 ppm |
| 16. Tapped density | 0.90 g/cc | As per customer requirements |
| Remark: The product complies as per above EP specifications. | | |
| This material has been manufactured in compliance with EU GMP requirements and Certificate no. R1-CEP 1998-101-Rev 01 | | |
| Checked by  | | Approved by  29.09.12 |

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