

CERTIFICATE OF ANALYSIS .

| TEST | RESULTS | REQUIREMENTS |
|-----------------------------|--|---|
| Characteristics | Passes | White to off white crystalline powder. |
| | Passes | Practically insoluble in water soluble in alcohol & in acetone. |
| Identification | Confirmed | By IR spectroscopy. |
| X-ray Diffraction | Passes | As per USP |
| Acidity | Passes | Max.1.0ml |
| Alkalinity | Passes | Max.1.0ml |
| Loss on Drying | 0.12% | Max. 0.5% |
| Residue on ignition | 0.058% | Max.0.1% |
| Chloride | Passes | As per USP |
| Chromatography purity | Passes | Max. 0.2% for single impurity |
| | | Max. 0.5% for total impurity |
| Organic Volatile Impurities | Passes | As per USP |
| Assay | 99.7% | bet. 98.0% to 102.0% (calculated on dry basis) |
| Water | Not more than 2.0% | 0.8% |
| Residue on ignition | Not more than 3.0% | 0.16% |
| Heavy Metals | Not more than 0.002% | <0.002% |
| Assay (On anhydrous basis) | Between 960 & 1040 mcg/mg C ₃₈ H ₆₉ NO ₁₃ per mg | 1026 mcg/mg |