



CERTIFICATE OF ANALYSIS

Product name: Vitamin B₆ (Pyridoxine Hydrochloride)

Lot: TN23092036

Manufacturing date: Sep 21, 2023
Retest date: Sep 20, 2027
Package: 25 kg per carton
Article No.: 03102

Reporting date: Sep 26, 2023
Quantity: 2,000 kg
Package size: 390 × 290 × 320 (mm)
Irradiation / ETO treatment: No

| Test Item | Specification | Method | Result |
|--|---|---------------|---|
| Appearance | A white or almost white crystalline powder | Visual | Conforms |
| Identification | | | |
| Infrared absorption | Consistent with the reference IR spectra | USP | Consistent with the reference IR spectra |
| Reaction of chlorides | A white curdy precipitate is formed with silver nitrate, the precipitate is insoluble in nitric acid but dissolves readily in ammonia | USP | A white curdy precipitate is formed with silver nitrate, the precipitate is insoluble in nitric acid but dissolves readily in ammonia |
| Appearance of solution | Clear, not more intense than Y ₇ | EP | Clear, not more intense than Y ₇ |
| pH | 2.4 ~ 3.0 | EP | 2.6 |
| Loss on drying | NMT 0.5% | USP | 0.03% |
| Residue on ignition | NMT 0.1% | USP | 0.02% |
| Chloride | 16.9% ~ 17.6% | USP | 17.3% |
| Residual solvent - Ethanol | NMT 0.5% | USP | <0.03% |
| Related substances (Disregard limit: 0.05%) | | | |
| - Impurity B | NMT 0.15% | EP | Comply |
| - Unspecified Impurity | NMT 0.10% | | Comply |
| - Total Impurities | NMT 0.2% | | Comply |
| Assay (on dry basis) | 98.0% ~ 102.0% | USP | 99.9% |
| Heavy metals | | | |
| Lead | ≤0.5 mg/kg | AAS, in-house | <0.5 mg/kg |
| Cadmium | ≤0.5 mg/kg | AAS, in-house | <0.5 mg/kg |
| Arsenic | ≤0.5 mg/kg | AAS, in-house | <0.5 mg/kg |
| Mercury | ≤0.1 mg/kg | AAS, in-house | <0.1 mg/kg |
| Microbials | | | |
| Total Aerobic Microbial Count | NMT 100 cfu/g | ChP | <100 cfu/g |
| Total Yeasts and Moulds Count | NMT 10 cfu/g | ChP | <10 cfu/g |
| E. Coli | Negative | ChP | Negative |
| Salmonella | Negative | ChP | Negative |
| S. Aureus | Negative | ChP | Negative |
| Conclusion: This batch was analyzed and found to meet the specifications as given above. | | | |
| Compendial compliance guarantee This material meets all requirements of the following valid compendia when tested accordingly: BP, EP, USP, FCC | | | |
| Remark: Preserve in a tightly closed container, protected from light. | | | |

Reported by: 刘勤平

Approved by: 陈庆峰