**Cetirizine DiHCl EP10.0**

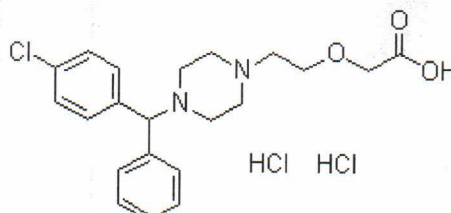| | |
|---|---|
| Batch no | 241006-33 |
| Mf date | Oct 10 2024 |
| Retest | Oct 09 2029 |

Molecular Structure



Molecular Formula $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$
Molecular Weight 461.81
CAS Registry Number 83881-52-1

Feb 10 2025

| Tests | Specifications | | Results |
|---|---|---|---|
| Appearance | White or off-white powder | | Conforms |
| Solubility | Soluble in water, almost insoluble in dichloromethane or acetone | | Conforms |
| Identification | IR, UV | | Positive |
| Related substances | Impurity A | ≤ 0.15% | ND |
| | Impurity B | ≤ 0.15% | ND |
| | Impurity C | ≤ 0.15% | ND |
| | Impurity D | ≤ 0.15% | ND |
| | Impurity E | ≤ 0.15% | ND |
| | Impurity F | ≤ 0.15% | ND |
| | Individual unknown impurity | ≤ 0.10% | ND |
| | Total impurity | ≤ 0.30% | ND |
| Loss on drying | ≤ 0.5% | | 0.4% |
| Residue on ignition | ≤ 0.2% | | 0.1% |
| pH | 1.2 ~ 1.8 | | 1.5 |
| Residual solvents | Acetone | ≤0.5% | < 0.1% |
| | Methylene chloride | ≤0.06% | < 0.01% |
| | Benzene | ≤0.0002% | ND |
| | Toluene | ≤0.089% | 0.005% |
| | N,n-Dimethylformamide | ≤0.088% | 0.017% |
| Assay (odb) | 99.0 ~ 101.0% of $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$ | | 99.3% |

| | |
|---|---|
| Packaging & storage | Preserve in tight containers and store in a dry place |
| Conclusion | Material complies with EP10.0 |