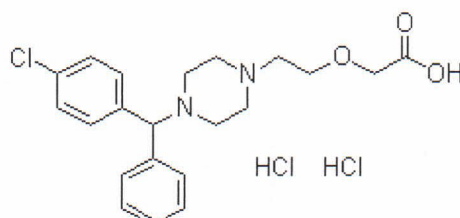


Batch no 231008-3  
Mf date Oct 10 2023  
Retest Oct 09 2028

### Molecular Structure



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

Mar 12 2024

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 $\leq 0.15\%$ Impurity B $\leq 0.15\%$ Impurity C $\leq 0.15\%$ Impurity D $\leq 0.15\%$ Impurity E $\leq 0.15\%$ Impurity F $\leq 0.15\%$ Individual unknown impurity $\leq 0.10\%$ Total impurity $\leq 0.30\%$	ND ND ND ND ND ND ND ND
Loss on drying	$\leq 0.5\%$	0.4%
Residue on ignition	$\leq 0.2\%$	0.1%
pH	1.2 ~ 1.8	1.3
Residual solvents	Acetone $\leq 0.5\%$ Methylene chloride $\leq 0.06\%$ Benzene $\leq 0.0002\%$ Toluene $\leq 0.089\%$ N, n-Dimethylformamide $\leq 0.088\%$	< 0.1% < 0.01% ND 0.003% 0.019%
Assay (odb)	99.0 ~ 101.0% of $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$	99.2%

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