

Cetirizine DiHCI EP10.0

Batch no

250226-2

Mf date

Feb 28 2025

Retest

Feb 27 2030

Molecular Structure

Molecular Formula C₂₁H₂₅CIN₂O₃·2HCI

Molecular Weight 461.81

CAS Registry Number 83881-52-1

Mar 21 2025

Tests	<u>Specifications</u>		Results
Appearance	White or off-white powder		Conforms
Solubility	Soluble in water, almost insoluble in		Conforms
	dichloromethane or aceton	е	
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%
Н	1.2 ~ 1.8		1.6
Residual solvents	Acetone	≤0. 5%	< 0.2%
	Methylene chloride	≤0. 06%	< 0.02%
	Benzene	≤0. 0002%	ND
	Toluene	≤0. 089%	0. 008%
	N, n-Dimethylformamide		0. 015%
Assay (odb)	99.0 $^{\sim}$ 101.0% of $C_{21}H_{25}CIN_2O_3$		99. 5%

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

