

### Certificate of Analysis

Product Name and grade	: Cetirizine Dihydrochloride USP	License No.	: KD-129
Batch No.	: SLL/CTR/0623023	Month of Manufacturing	: June - 2023
Batch Qty.	: 395.600 Kg	Month of re-test / expiry	May - 2028
Dispatch Qty	: 25.000 Kg		
A. R. No.	: SLL/QC/FP/23/1536	Date of Release	: 07/07/2023

Sr.No.	Test	Specifications	Results
1.	Characters		
1.1	Appearance	White to almost white powder	White powder.
1.2	Solubility	Freely soluble in water; practically insoluble in acetone and in methylene chloride	Conforms
2.	Identification:		
2.1	Test A: IR	The infra red absorption spectrum should be concordant with that of Cetirizine Dihydrochloride working standard or reference standard.	Complies
2.2	Test B: Chloride	It should give reaction of chlorides	Complies
2.3	Test C: Retention time by HPLC	The retention times of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies
3.	Tests		
3.1	Assay by HPLC on dry basis (%)	Not less than 98.0 Not more than 102.0	99.72
3.2	Residue on ignition (% w/w)	Not more than 0.2	0.08
3.3	Organic impurities by HPLC (%) (Procedure 2)		
	Deschlorocetirizine	Not more than 0.1	BDL
	Cetirizine ethanol	Not more than 0.1	BDL
	CBHP	Not more than 0.1	BDL
	2-Chlorocetirizine	Not more than 0.1	BDL
	Cetirizine methyl ester	Not more than 0.1	BDL
	3-Chlorocetirizine	Not more than 0.1	BDL
	Cetirizine acetic acid	Not more than 0.1	BDL
	Cetirizine N-oxide	Not more than 0.1	BDL
	4-CBH	Not more than 0.1	BDL
	4-Chlorobenzophenone	Not more than 0.1	BDL
	Cetirizine dimer	Not more than 0.1	BDL
	Any individual unspecified impurities	Not more than 0.10	BDL
	Total impurities	Not more than 0.3	BDL



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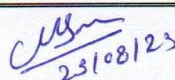
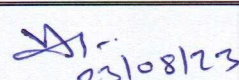
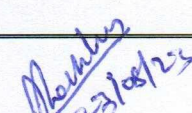
Sr.No.	Test	Specifications	Results
3.4	pH (1 in 20 aqueous solution)	1.2 - 1.8	1.50
3.5	Loss on drying at 105°C for constant weight (% w/w).	Not more than 0.5	0.17
4.	Additional test:		
4.1	Residual Solvents by GC-HS (ppm)		
	Methanol	Not more than 3000	BDL
	Acetone	Not more than 5000	46
	Methylene chloride	Not more than 600	BDL
	Ethyl Acetate	Not more than 5000	BDL
	Chloroform	Not more than 60	BDL
	Benzene	Not more than 2	BDL
	Toluene	Not more than 890	BDL
	Dimethylformamide	Not more than 880	BDL
4.2	Triethylamine content by GC-HS (ppm)	Not more than 490	BDL

Where,

BDL: Below Detection Limit For Organic impurities by HPLC

BDL: Below Detection Limit For Residual Solvent by GC-HS.

**Remarks:** The product complies with respect to above mentioned tests as per grade **USP NF 2023**.**Storage Condition:** Preserve in tight containers, protected from light and moisture. Store at room temperature.

 Prepared by QA Chemist (M.M.Ambre)	 Checked by QA Sr.Executive (V.A.Sawant)	 Approved by Head-QA/Designee Head QA (Sheshhu kumar Kalidindi)
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