PRAVEEN LABORATORIES PVT. LTD.

Block No. 206, Moje-Jolwa, Taluka- Palsana, District –Surat. 394 305(INDIA)

PLPL / Quality Assurance
Dispatch Date: 22/11/2025
Sign.:

CERTIFICATE OF ANALYSIS

Product Name	: Cetirizine Dihydrochloride EP		
Batch No.	: MK30125046	**A. R. No.**	: QC/FP/300/25
Mfg. Date	: May 2025	**Qty.**	: 01 x 15.00 Kg
Exp. Date	: April 2030	**Date**	: 04/11/2025
Reference	: EP		

Sr. No	Tests	Observations	Specifications
1.	Description	White powder	White or almost white powder.
2.	Solubility	Freely soluble in water, practically insoluble in acetone, and in methylene chloride.	Freely soluble in water, practically insoluble in acetone, and in methylene chloride.
3.	Identification		
	A. By UV	Solution is showing absorption maximum at 231.4 nm. The specific absorbance is 367.79 at 231.4 nm	A. Solution should show absorption maximum at 231 nm. The specific absorbance should be between 359 to 381 at 231 nm.
	B. By IR	IR spectrum of the test sample is concordant with IR spectrum of Cetirizine Dihydrochloride standard.	B. IR spectrum of the test sample should be concordant with IR spectrum of Cetirizine Dihydrochloride standard.
	C. By Thin Layer Chromatography	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).	C. The principal spot in the chromatogram obtained with the test solution should be similar in position and size to the principal spot in the chromatogram obtained with reference solution (a).
	D. By Reaction of Chloride	It gives reaction of chlorides	D. It should give reactions of chlorides
4.	Appearance of Solution	Solution S is clear and not more intensely colored than reference solution BY_7.	Solution S should be clear and not more intensely colored than reference solution BY_7.
5.	pH	1.36	Between 1.2 to 1.8
6.	Loss On Drying	0.21	Not more than 0.5% w/w.

Sign & Date	04/11/2025	04/11/2025	R Patel 04/11/2025
	Prepared By	**Reviewed By**	**Approved By**
Name	Nilkanth Patil	Himanshu Patel	Rajendra Patil
Designation	Officer QA	Asst. Manager QC	Manager QA

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Sr. No	Tests	Observations	Specifications
7.	Sulphated Ash	0.03	Not more than 0.2% w/w.
8.	Related Substances (By HPLC)	ND	Impurity A : NMT 0.15%
		BLQ	Impurity B : NMT 0.15%
		0.03	Impurity C : NMT 0.15%
		ND	Impurity D : NMT 0.15%
		0.03	Impurity E : NMT 0.15%
		ND	Impurity F : NMT 0.15%
		Maximum Individual 0.04	Unknown Impurity : NMT 0.10%
		0.14	Total Impurities : NMT 0.3%
9.	Assay by potentiometery (On Dried Basis)	100.5	Between 99.0% to 101.0% w/w as $C_{21}H_{27}Cl_3N_2O_3$
Additional Tests:			
10.	Residual Solvents (By GC) Method-I	BLQ	Methanol : NMT 3000 ppm
		BLQ	Acetone : NMT 5000 ppm
		BLQ	Methylene Chloride : NMT 600 ppm
		ND	Toluene : NMT 890 ppm
		ND	Dimethyl Formamide : NMT 880 ppm
		ND	Mesityl Oxide : NMT 100 ppm
		ND	2-Chloroethanol : NMT 200 ppm
		ND	Benzene : NMT 2 ppm
11.	Residual Solvents (By GC) Method-II	ND	Tri Ethylamine : NMT 5000 ppm

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Storage Condition: Preserve in tight containers, protect from light and moisture.

Abbreviations:

UV= Ultraviolet, HPLC= High performance liquid chromatography, IR = Infrared spectroscopy, nm = Nanometer, ppm = Parts per Million, GC= Gas Chromatography, NMT= Not more than, BLQ= below level of quantification, ND=Not Detected, Cfu/g= Colony forming unit per gram.

Impurities:

Impurity A= (*RS*)-1-[(4-chlorophenyl)phenylmethyl]piperazine.
Impurity B= (*RS*)-2-[4-[(4-chlorophenyl)phenylmethyl]piperazin-1-yl]acetic acid.
Impurity C= (*RS*)-2-[2-[4-[(2-chlorophenyl)phenylmethyl]-piperazin-1-yl]ethoxy]acetic acid.
Impurity D= 1,4-bis[(4-chlorophenyl)phenyl methyl] piperazine
Impurity E= (*RS*)-2-[2-[2-[4-[(4-chlorophenyl)phenylmethyl]-piperazin-1-yl]ethoxy]ethoxy] acetic acid .
Impurity F= [2-[4-(diphenylmethyl)piperazin-1-yl]ethoxy]acetic acid.

Remarks: The product complies / ~~does not comply~~ with the above mentioned specifications.

CAS NO.: [83881-52-1]

Sign & Date	04/11/2025	04/11/2025	04/11/2025
	Prepared By	**Reviewed By**	**Approved By**
Name	Nilkanth Patil	Himanshu Patel	Rajendra Patil
Designation	Officer QA	Asst. Manager QC	Manager QA

Revision No.: R-01