

METAPHARMACEUTICAL

N DE LOTE:

0250424

25/04/2024



QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
FINISHED GOODS			
Product Name : CETIRIZINE DIHYDROCHLORIDE Ph. Eur.			
Batch No. :	23015CZ6RII	Batch Size :	206.50 Kgs.
Mfg Date :	Sep/2023	Retest Date :	NA
Expiry Date :	Aug/2028	A.R.No. :	IBD-234091
LIMS AR No.:	2102-9931	LIMS Specification Id.:	2102-197
Page No. :	1 of 2	Specification No./ Revision No.:	TS/BPC/CZ6/CS/COS/01/0

Tests	Specifications	Results
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Characters (Appearance)	A white or almost white powder.	White powder.
Characters (Solubility)	Freely soluble in water, practically insoluble in acetone and in methylene chloride.	Conforms
Identification 1	The infrared absorption spectrum of sample and standard are concordant.	Conforms
Identification 2	It given reaction (a) of chlorides.	Conforms
Appearance of Solution	Solution is clear and not more intensely coloured than reference solution BY ₇ .	Conforms
pH	pH 1.2 to 1.8.	1.47
Related Substances (By HPLC)	Impurity A:NMT 0.15%	<0.05%
	Impurity B:NMT 0.15%	<0.05%
	Impurity C:NMT 0.15%	<0.05%
	Impurity D:NMT 0.15%	Not Detected
	Impurity E:NMT 0.15%	0.05%
	Impurity F:NMT 0.15%	<0.05%

Checked By (QC)	AMIT SINGH (Manager QC)	Approved By (QA)	RAJENDRA SINGH (Manager QA)
Checked On	03/10/2023 15:04	Approved On	04/10/2023 14:41
Printed By : RAJENDRA SINGH	Printed on :	04/10/2023 14:50	Copy No. : 1
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Tests	Specifications	Results
	Impurity G:NMT 0.10%	<0.05%
	Cetirizine methyl ester:NMT 0.10%	<0.05%
	3-Chlorocetirizine :NMT 0.10%	<0.05%
	Cetirizine N-oxide:NMT 0.10%	Not Detected
	4-CBH:NMT 0.10%	Not Detected
	4-Chlorobenzophenone:NMT 0.10%	Not Detected
	Any Unspecified Impurity:NMT 0.10%	<0.05%
	Total Impurities:NMT 0.30%	0.05 %
Loss On Drying (at 105°C)	NMT 0.5% w/w	0.26 %w/w
Sulphated Ash	NMT 0.2% w/w.	0.04 %w/w
Assay	99.0% - 101.0% of $C_{21}H_{27}Cl_3N_2O_3$ (on dried basis)	99.7 %
Residual Solvents	*Acetone : NMT 5000 ppm *Acetone being Class III solvent, is limited by the Test for Loss on Drying to a limit of NMT 0.5%.	-
REMARKS : The sample CONFORMS with respect to the above specifications		

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