

METAPHARMACEUTICAL

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QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
FINISHED GOODS			
Product Name : CETIRIZINE DIHYDROCHLORIDE Ph. Eur.			
Batch No. :	22061CZ6R11	Batch Size :	230.50 Kg
Mfg Date :	Feb/2023	Retest Date :	NA
Expiry Date :	Jan/2028	A.R.No. :	IBD-230761
Lims AR No.:	2102-50104	LIMS Specification ID.:	2102-17
Page No.:	1 of 2	Specification No.:	TS/BPC/CZ6/CS/CO S/01

Tests	Results	Specifications
Characters (Appearance)	White powder	A white or almost white powder.
Characters (Solubility)	Conforms	Freely soluble in water, practically insoluble in acetone and in methylene chloride.
Identification 1	Conforms	The infrared absorption spectrum of sample and standard are concordant.
Identification 2	Conforms	It given reaction (a) of chlorides.
Appearance of Solution	Conforms	Solution is clear and not more intensely coloured than reference solution BY ₇ .
pH	1.63	1.2 to 1.8.
Related Substances (By HPLC)	<0.05%	Impurity A NMT 0.15%
	<0.05%	Impurity B NMT 0.15%
	<0.05%	Impurity C NMT 0.15%
	Not Detected	Impurity D NMT 0.15%
	0.05%	Impurity E NMT 0.15%
	<0.05%	Impurity F NMT 0.15%
	<0.05%	Impurity G NMT 0.10%
	<0.05%	Cetirizine methyl ester NMT 0.10%

Checked By (QC)	Indrajeet Singh Panwar	Approved By (QA)	Himanshu Bhopte
Checked On	09/Mar/2023 16:26	Approved On	13/Mar/2023 11:55
Printed By : Himanshu Bhopte	Printed on :	13/03/2023 12:03	Copy No. : 1
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 E: ipca@ipca.com CIN: L24239MH1949PLC007837

QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
FINISHED GOODS			
Product Name : CETIRIZINE DIHYDROCHLORIDE Ph. Eur.			
Batch No :	22061CZ6RII	Batch Size :	230.50 Kg
Mfg Date :	Feb/2023	Retest Date :	NA
Expiry Date :	Jan/2028	A.R.No. :	IBD-230761
Lims AR No.:	2102-50104	LIMS Specification ID.:	2102-17
Page No.:	2 of 2	Specification No.:	TS/BPC/CZ6/CS/CO S/C1

Tests	Results	Specifications
	<0.05%	3-Chlorocetirizine NMT 0.10%
	Not Detected	Cetirizine N-oxide NMT 0.10%
	Not Detected	4-CBH NMT 0.10%
	Not Detected	4-Chlorobenzophenone NMT 0.10%
	<0.05%	Any Unspecified Impurity NMT 0.10%
	0.05%	Total Impurities NMT 0.30%
Loss On Drying (at 105°C)	0.27 %w/w	NMT 0.5% w/w
Sulphated Ash	0.06 %w/w	NMT 0.2% w/w.
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%.
Assay	99.9 %	99.0% - 101.0% of $C_{21}H_{27}Cl_3N_3O_3$ (on dried basis)
REMARKS : The sample CONFORMS with respect to the above specifications		

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