

Ciserano, 25/01/2016 ANALYSIS No. F714/2015		BATCH No. 114315002		
Manufacturing date: December 2015		Retest date: December 2020		Batch size: 280,00 Kg
PRODUCT		CETIRIZINE DIHYDROCHLORIDE CAS N. 83881-52-1		
Physical State: crystalline powder Colour: white or almost white Odour: Solubility: Freely soluble in Water, practically insoluble in Acetone and Methylene Chloride.		Molecular weight: 461.8 Formula: C ₂₁ H ₂₇ ClN ₂ O ₃ Method No. 1143/1		
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION I.R. spectrum	Positive		Positive	
Melting point	209,6 - 210,5		209,0 - 212,0 °C	
pH (5% in water)	1.55		min. 1,2 max. 1,8	
Clarity of solution Colour of solution	Clear n.m.t. brown-yellow 7		Clear n.m.t. Brown-Yellow degree 7	
Specific rotation	0.0319 °		-0,10° +0,10°	
Heavy metals	n.m.t. 10 ppm		n.m.t. 10 ppm	
Loss on drying	0.12 %		n.m.t. 0,5%	
Sulphated ash	0.063 %		n.m.t. 0,2%	
ASSAY NaOH 0,1N	99.31 %		min. 99,0% max. 100,5%	
HPLC (on dried substance)	99.99 %	min.98,0% max.102,0%		

Qualified Person

Quality Control Manager

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Chlorides	15.30 %		min. 15,20% max. 15,43%	
Foreign substances	n.m.t. 10 ppm		n.m.t. 10 ppm	
Particle size (Malvern)				Declare the found value
d(0.5)	3.59 mcm			Declare the found value
d(0.9)	8.35 mcm			Declare the found value
Bulk density	0.23 g/ml			Declare the found value
Tapped density	0.28 g/ml			Declare the found value
RESIDUAL SOLVENTS				
Acetone	57.2 ppm			n.m.t. 1000 ppm
Related substances (HPLC)				
Labelled Impurities				
Dimer	Not detectable		n.m.t. 0,1%	
Desethoxycetirizine	0.04 %		n.m.t. 0,1%	
N-Oxide	0.01 %		n.m.t. 0,1%	
2-Chlorocetirizine	0.03 %		n.m.t. 0,1%	
Ethoxycetirizine	0.03 %		n.m.t. 0,1%	
Deschlorocetirizine	Not detectable		n.m.t. 0,1%	
IDZ1	0.01 %		n.m.t. 0,1%	
Cet12	0.13 %		n.m.t. 0,1%	
Unknown Impurity Max	0.04 %		n.m.t. 0,10%	

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Total Impurities	0.30 %		n.m.t. 0,3%	
Related Substances (USP)				
Labelled Impurities				
Deschlorocetirizine	Not detectable	n.m.t. 0,1%		n.m.t. 0,1%
Cet ₂	0.06 %	n.m.t. 0,1%		n.m.t. 0,1%
IDZ ₁	0.01 %	n.m.t. 0,1%		n.m.t. 0,1%
2-Chlorocetirizine	Not detectable	n.m.t. 0,1%		n.m.t. 0,1%
Cetirizine methyl ester	0.01 %	n.m.t. 0,1%		n.m.t. 0,10%
3-Chlorocetirizine	Not detectable	n.m.t. 0,1%		n.m.t. 0,10%
Desethoxycetirizine	0.02 %	n.m.t. 0,1%		n.m.t. 0,1%
Cetirizine N-oxide	Not detectable	n.m.t. 0,1%		n.m.t. 0,1%
4-Chlorobenzhydrol	Not detectable	n.m.t. 0,1%		n.m.t. 0,1%
4-Chlorobenzophenone	Not detectable	n.m.t. 0,1%		n.m.t. 0,1%
Cetirizine dimer	Not detectable	n.m.t. 0,1%		n.m.t. 0,1%
Unknown Impurity Max	0.01 %	n.m.t. 0,10%		n.m.t. 0,10%
Total Impurities	0.11 %	n.m.t. 0,3%		n.m.t. 0,3%

We hereby certify that the above identified material has been analysed and found in accordance with the specification of the current European Pharmacopoeia.

Qualified Person

Quality Control Manager

Release date: 27/01/2016