

Ciserano, 15/12/2017				
ANALYSIS No. F610/2017		BATCH No. 114317002		
Manufacturing date: November 2017		Relest date: November 2022		Batch size: 225,00 Kg
PRODUCT		CETIRIZINE DIHYDROCHLORIDE CAS N. 83881-52-1		
Physical State: crystalline powder		Molecular weight: 481.8		
Colour: white or almost white		Formula : C21H27Cl3N2O3		
Odour:		Method No. 1143/1		
Solubility: Freely soluble in Water, practically insoluble in Acetone and Methylene Chloride.				
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION I.R. spectrum	Positive		Positive	
Melting point	209.8°C - 210.7°C		209,0 - 212,0 °C	
pH (5% in water)	1.49		min. 1,2 max. 1,8	
Clarity of solution Colour of solution	clear n.m.l. brown-yellow degree 7		Clear n.m.l. Brown-Yellow degree 7	
Specific rotation	0.0360 °		-0,10° +0,10°	
Heavy metals	n.m.l. 10 ppm		n.m.l. 10 ppm	
Loss on drying	0.15 %		n.m.l. 0,5%	
Sulphated ash	0.019 %		n.m.l. 0,2%	
ASSAY NaOH 0.1N	99.84 %		min. 99,0% max: 100,5%	
HPLC (on dried substance)	100.44 %	min.98,0% max.102,0%		
Chlorides	15.31 %		min. 15,20% max. 15,43%	

Qualified Person

Quality Control Manager

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PRODUCT		CETIRIZINE DIHYDROCHLORIDE CAS N. 83881-52-1		
Physical State: crystalline powder		Molecular weight: 461.8		
Colour: white or almost white		Formula : C21H27Cl3N2O3		
Odour:		Method No. 1143/1		
Solubility: Freely soluble in Water, practically Insoluble in Acetone and Methylene Chloride.				
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Foreign substances	n.m.l. 10 ppm		n.m.l. 10 ppm	
Particle size (Malvern)				
d(0.5)	2.39 mcm			Declare the found value
d(0.9)	6.88 mcm			Declare the found value
Bulk density	0.17 g/ml			Declare the found value
Tapped density	0.25 g/ml			Declare the found value
RESIDUAL SOLVENTS				
Acetone	90.2 ppm			n.m.l. 1000 ppm
Related substances (HPLC)				
Labelled Impurities				
Dimer	Not detectable		n.m.l. 0,1%	
Desethoxycetirizine	0.02 %		n.m.l. 0,1%	
N-Oxide	Not detectable		n.m.l. 0,1%	
2-Chlorocetirizine	Not detectable		n.m.l. 0,1%	
Ethoxycetirizine	Not detectable		n.m.l. 0,1%	
Deschlorocetirizine	Not detectable		n.m.l. 0,1%	
IDZ1	0.01 %		n.m.l. 0,1%	
Cet12	0.08 %		n.m.l. 0,1%	
Unknown Impurity Max	0.06 %		n.m.l. 0,10%	
Total Impurities	0.17 %		n.m.l. 0,3%	
Related Substances (USP)				
Labelled Impurities				

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Deschlorocetirizine	0.01 %	n.m.l. 0,1%		n.m.l. 0,1%
Ceti2	0.07 %	n.m.l. 0,1%		n.m.l. 0,1%
IDZ1	0.03 %	n.m.l. 0,1%		n.m.l. 0,1%
2-Chlorocetirizine	Not detectable	n.m.l. 0,1%		n.m.l. 0,1%
Cetirizine methyl ester	Not detectable	n.m.l. 0,1%		n.m.l. 0,10%
3-Chlorocetirizine	Not detectable	n.m.l. 0,1%		n.m.l. 0,10%
Desethoxycetirizine	0.02 %	n.m.l. 0,1%		n.m.l. 0,1%
Cetirizine N-oxide	Not detectable	n.m.l. 0,1%		n.m.l. 0,1%
4-Chlorobenzhydrol	Not detectable	n.m.l. 0,1%		n.m.l. 0,1%
4-Chlorobenzophenone	Not detectable	n.m.l. 0,1%		n.m.l. 0,1%
Cetirizine dimer	Not detectable	n.m.l. 0,1%		n.m.l. 0,1%
Unknown Impurity Max	0.06 %	n.m.l. 0,10%		n.m.l. 0,10%
Total Impurities	0.20 %	n.m.l. 0,3%		n.m.l. 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: 19/12/2017