

Ciserano, 26/07/2021				
ANALYSIS No. F567/2021		BATCH No. 110721029		
Manufacturing date: June 2021		Retest date: June 2026		Batch size: 586,00 Kg
PRODUCT		HYDROXYZINE HYDROCHLORIDE CAS N. 2192-20-3		
Physical State: powder Colour: white Odour: odourless Solubility: Very soluble in Water, soluble in Chloroform, slightly soluble in Acetone and practically insoluble in Ethyl Ether.		Molecular weight: 447.83 Formula : C21H27ClN2O2.2HCl Method No. 1107/1		
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION				
I.R. spectrum	Positive	Positive	Positive	
UHPLC	Positive	Positive		
Chlorides test	Positive	Positive	Positive	
Clarity of solution	Clear		Clear	
Colour of solution	n.m.t. yellow degree 7		n.m.t. yellow degree 7	
Melting point	199.3 °C - 200.0 °C			about 200°C with decomposition
Specific rotation	-0.0066 °		min. -0,10° max. +0,10°	
Loss on drying	0.33 %		n.m.t. 5,0%	
Water (K.F. method)	1.24 %	n.m.t. 5,0%		
Residue on ignition	0.144 %	n.m.t. 0,5%	n.m.t. 0,1%	
ASSAY				
HClO4 0,1N (on dried substance)	99.68 %		min. 99,0% max. 101,0%	min. 98,0% max. 100,5%
UHPLC (on anhydrous substance)	99.79 %	min. 98,0% max. 102,0%		
Related substances				
Labelled Impurities				
IDZ1	Not detectable	n.m.t. 0,3%	n.m.t. 0,1%	
Deschlorohydroxyzine	Not detectable	n.m.t. 0,3%	n.m.t. 0,1%	
4-Chlorobenzophenone	Not detectable	n.m.t. 0,2%		
Other Impurities				
Dimer	Not detectable	n.m.t. 0,2%		n.m.t. 0,1%

Qualified Person

Quality Control Manager

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
<i>Desethoxyhydroxyzine</i>	0.01 %	n.m.t. 0.2%		n.m.t. 0,1%
<i>Ethoxyhydroxyzine</i>	Not detectable	n.m.t. 0.2%		n.m.t. 0,1%
Unknown Impurity Max	0.01 %	n.m.t. 0.2%		n.m.t. 0,10%
Total Impurities	0.06 %	n.m.t. 0.75%	n.m.t. 0,3%	
RESIDUAL SOLVENTS				
<i>Acetone</i>	Not detectable			n.m.t. 500 ppm
<i>Isobutyl Alcohol</i>	Not quantifiable			n.m.t. 1000 ppm
<i>Methylisobutylketone</i>	52.6 ppm			n.m.t. 500 ppm
Bulk density	0.20 g/ml			min. 0,15 g/ml max. 0,30 g/ml
Tapped density	0.32 g/ml			min. 0,25 g/ml max. 0,55 g/ml
Foreign substances	n.m.t. 10 ppm			n.m.t. 10 ppm
Particle size	75.3 %			n.l.t. 50% passes 200 mcm

Qualified Person

Quality Control Manager

Release date: 02/08/2021