

Ciserano, 06/05/2020
ANALYSIS No. F229/2020
BATCH No. 110720012

 Manufacturing date: **February 2020**

 Retest date: **February 2025**

 Batch size: **808,00 Kg**
PRODUCT
HYDROXYZINE HYDROCHLORIDE
CAS N. 2192-20-3
Physical State: powder

Molecular weight: 447.83

Colour: white

Formula : C₂₁H₂₇ClN₂O₂·2HCl

Odour: odourless

Method No. 1107/1

Solubility: Very soluble in Water, soluble in Chloroform, slightly soluble in Acetone and practically insoluble in Ethyl Ether.

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	198.2 °C - 201.4 °C			about 200°C with decomposition
Specific rotation	0.0178 °		min. -0,10° max. +0,10°	
Loss on drying	0.11 %		n.m.t. 5,0%	
Water (K.F. method)	0.28 %	n.m.t. 5,0%		
Residue on ignition	0.020 %	n.m.t. 0,5%	n.m.t. 0,1%	
ASSAY				
HClO ₄ 0,1N (on dried substance)	100.11 %		min. 99,0% max. 101,0%	min. 98,0% max. 100,5%
UHPLC (on anhydrous substance)	100.39 %	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 quantifiable	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

Ciserano, 06/05/2020				
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Manufacturing date: February 2020		Retest date: February 2025		Batch size: 808,00 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
Desethoxyhydroxyzine	0.01 %	n.m.t. 0.2%		n.m.t. 0,1%
Ethoxyhydroxyzine	Not detectable	n.m.t. 0.2%		n.m.t. 0,1%
Unknown Impurity Max	0.02 %	n.m.t. 0.2%		n.m.t. 0,10%
Total Impurities	0.08 %	n.m.t. 0.75%	n.m.t. 0,3%	
RESIDUAL SOLVENTS				
Acetone	Not detectable			n.m.t. 500 ppm
Isobutyl Alcohol	Not quantifiable			n.m.t. 1000 ppm
Methylisobutylketone	104.8 ppm			n.m.t. 500 ppm
Bulk density	0.19 g/ml			min. 0,15 g/ml max. 0,30 g/ml
Tapped density	0.29 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	95.3 %			n.l.t. 50% passes 200 mcm

Qualified Person

Quality Control Manager

Release date: 08/05/2020