

Ciserano, 15/07/2024

ANALYSIS No. F566/2024
BATCH No. 110724025

Manufacturing date: 10 May 2024

Retest date: 10 May 2029

Batch size: 800,00 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	199.8 °C - 200.1 °C			about 200°C with decomposition
Specific rotation	0.0578 °		min. -0,10° max. +0,10°	
Loss on drying	0.68 %		n.m.t. 5,0%	
Water (K.F. method)	1.19 %	n.m.t. 5,0%		
Residue on ignition	0.024 %	n.m.t. 0,5%	n.m.t. 0,1%	
ASSAY				
HClO ₄ 0,1N (on dried substance)	99.68 %		min. 99,0% max. 101,0%	min. 99,0% max. 100,5%
UHPLC (on anhydrous substance)	100.53 %	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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Colour: white		Formula : C ₂₁ H ₂₇ CIN ₂ O ₂ .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
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	0.03 %	n.m.t. 0.2%		n.m.t. 0,10%
Total Impurities	0.10 %	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	78.4 ppm			n.m.t. 500 ppm
Bulk density	0.17 g/ml			min. 0,15 g/ml max. 0,30 g/ml
Tapped density	0.33 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	93.4 %			n.l.t. 50% passes 200 mcm

Qualified Person

Quality Control Manager

Release date: 16/07/2024