

Ciserano, 26/11/2014

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ANALYSIS No. F296/2014

BATCH No. 110714023

Manufacturing date: September 2014

Retest date: September 2019

Batch size: 795,00 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>I.R. spectrum</i>	Positive	Positive	Positive	
<i>Ultraviolet Absorptivities</i>	Positive	Positive		
<i>a230 nm sample</i>				
<i>a230 nm standard</i>				
<i>difference</i>	1.66 %	n.m.t. 3,0%		
<i>Chlorides test</i>	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	198.9 - 199.9			about 200°C with decomposition
Specific rotation	0.0378 °		min. -0,10° max. +0,10°	
Loss on drying	0.20 %	n.m.t. 5,0%	n.m.t. 5,0%	
Residue on ignition	0.008 %	n.m.t. 0,5%	n.m.t. 0,1%	
Heavy metals	n.m.t. 10 ppm	n.m.t. 20 ppm	n.m.t. 10 ppm	
ASSAY				
<i>HClO₄ 0,1N (on dried substance)</i>	99.77 %		min. 99,0% max. 101,0%	min. 98,0% max. 100,5%
<i>HPLC (on dried substance)</i>	99.93 %	min. 98,0% max. 102,0%		

Qualified Person

Quality Control Manager

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Related substances (HPLC)				
Labelled Impurities				
IDZ1	Not quantifiable	n.m.t. 0,3%	n.m.t. 0,1%	
Deschlorohydroxyzine	0.01 %	n.m.t. 0,3%	n.m.t. 0,1%	
Other Impurities				
Dimer	Not detectable			n.m.t. 0,1%
Desethoxyhydroxyzine	0.02 %			n.m.t. 0,1%
Ethoxyhydroxyzine	0.01 %			n.m.t. 0,1%
Unknown Impurity Max	0.03 %			n.m.t. 0,10%
Total Impurities	0.13 %	n.m.t. 1,5%	n.m.t. 0,3%	
RESIDUAL SOLVENTS				
Acetone	Not detectable			n.m.t. 500 ppm
Isobutyl Alcohol	11.0 ppm			n.m.t. 1000 ppm
Methylisobutylketone	16.8 ppm			n.m.t. 500 ppm
Bulk density	0.19 g/ml			min. 0,15 g/ml max. 0,30 g/ml
Tapped density	0.30 g/ml			min. 0,25 g/ml max. 0,55 g/ml
Foreign substances	n.m.t. 10 ppm			n.m.t. 10 ppm

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Particle size	55.8 %			n.l.t. 50% passes 200 mcm

Qualified Person

Quality Control Manager

Release date: 28/11/2014