



Ciserano, 09/03/2016

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ANALYSIS No. F50/2016**BATCH No. 110716001**Manufacturing date: **November 2015**Retest date: **November 2020**Batch size: **770,00 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>HPLC</i>	Positive	Positive		
<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	200.1 - 200.5			about 200°C with decomposition
Specific rotation	0.0080 °		min. -0,10° max. +0,10°	
Water (K.F. method)	0.07 %	n.m.t. 5,0%		
Loss on drying	0.03 %		n.m.t. 5,0%	
Residue on ignition	0.044 %	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>	99.59 %		min. 99,0% max. 101,0%	min. 98,0% max. 100,5%
<i>HPLC (on anhydrous substance)</i>	100.87 %	min. 98,0% max. 102,0%		

Qualified Person

Quality Control Manager

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Related substances (HPLC)				
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%	
Other Impurities				
Dimer	Not detectable			n.m.t. 0,1%
Desethoxyhydroxyzine	0.01 %			n.m.t. 0,1%
Ethoxyhydroxyzine	Not detectable			n.m.t. 0,1%
Unknown Impurity Max	0.01 %			n.m.t. 0,10%
Total Impurities	0.03 %	n.m.t. 1,5%	n.m.t. 0,3%	
RESIDUAL SOLVENTS				
Acetone	0.6 ppm			n.m.t. 500 ppm
Isobutyl Alcohol	19.0 ppm			n.m.t. 1000 ppm
Methylisobutylketone	32.4 ppm			n.m.t. 500 ppm
Bulk density	0.18 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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<i>Particle size</i>	90.2 %			n.l.t. 50% passes 200 mcm

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Quality Control Manager

Release date: 09/03/2016