

Ciserano, 21/10/2015

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ANALYSIS No. F549/2015

BATCH No. 110715033

Manufacturing date: **September 2015**

Retest date: **September 2020**

Batch size: **573,00 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	199.5 - 200.3			about 200°C with decomposition
Specific rotation	0.0259 °		min. -0,10° max. +0,10°	
Water (K.F. method)	0.71 %	n.m.t. 5,0%		
Loss on drying	0.39 %		n.m.t. 5,0%	
Residue on ignition	0.035 %	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 anhydrous substance)</i>	99.55 %	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				
<i>IDZ1</i>	Not quantifiable	n.m.t. 0,3%	n.m.t. 0,1%	
<i>Deschlorohydroxyzine</i>	Not detectable	n.m.t. 0,3%	n.m.t. 0,1%	
Other Impurities				
<i>Dimer</i>	Not detectable			n.m.t. 0,1%
<i>Desethoxyhydroxyzine</i>	0.02 %			n.m.t. 0,1%
<i>Ethoxyhydroxyzine</i>	Not detectable			n.m.t. 0,1%
Unknown Impurity Max	0.02 %			n.m.t. 0,10%
Total Impurities	0.10 %	n.m.t. 1,5%	n.m.t. 0,3%	
RESIDUAL SOLVENTS				
<i>Acetone</i>	8.2 ppm			n.m.t. 500 ppm
<i>Isobutyl Alcohol</i>	14.4 ppm			n.m.t. 1000 ppm
<i>Methylisobutylketone</i>	24.7 ppm			n.m.t. 500 ppm
Bulk density	0.17 g/ml			min. 0,15 g/ml max. 0,30 g/ml
Tapped density	0.30 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	87.4 %			n.l.t. 50% passes 200 mcm

Qualified Person

Quality Control Manager

Release date: 23/10/2015