



COSMA S.p.A.
Società con socio unico
Cap. Soc. € 954.600 i.v. - Cod. Fisc. / Part. IVA IT 00714610169
Via Colleoni, 15/17 - 24040 CISERANO (Bergamo) - ITALY
Telefono 035.88.30.55 - Telefax 035.482.05.01
E-mail: cosma@cosma.it - PEC: cosmaspa@legalmail.it

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Ciserano, 02/05/2016

ANALYSIS No. F170/2016

BATCH No. 110716013

Manufacturing date: February 2016

Retest date: February 2021

Batch size: 822,00 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	
HPLC	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	200.3 - 200.9			about 200°C with decomposition
Specific rotation	0.0560 °		min. -0,10° max. +0,10°	
Water (K.F. method)	0.50 %	n.m.t. 5,0%		
Loss on drying	0.12 %		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				
HClO ₄ 0,1N (on dried substance)	100.11 %		min. 99,0% max. 101,0%	min. 98,0% max. 100,5%
HPLC (on anhydrous substance)	99.19 %	min. 98,0% max. 102,0%		

Qualified Person

Quality Control Manager



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Odour: odourless		Method No. 1107/1		
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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	0.03 %			n.m.t. 0,10%
Total Impurities	0.06 %	n.m.t. 1,5%	n.m.t. 0,3%	
RESIDUAL SOLVENTS				
Acetone	261.9 ppm			n.m.t. 500 ppm
Isobutyl Alcohol	18.2 ppm			n.m.t. 1000 ppm
Methylisobutylketone	42.1 ppm			n.m.t. 500 ppm
Bulk density	0.23 g/ml			min. 0,15 g/ml max. 0,30 g/ml
Tapped density	0.38 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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Ciserano, 02/05/2016 ANALYSIS No. F170/2016		Page 3 / 3 BATCH No. 110716013		
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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Particle size	86.9 %			n.l.t. 50% passes 200 mcm



Qualified Person

Release date: 03/05/2016

Quality Control Manager