**C O S M A S.p.A.****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

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Page 1 / 2

Ciserano, 09-08-2010

ANALISI N. F0211/10

Analysis

LOTION. 110710015

Batch

Manufacturing date: June 2010

Expiry Date: June 2015

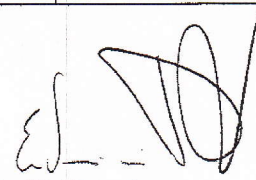
Batch size 800 Kg

PRODOTTO

Product

HYDROXYZINE HYDROCHLORIDE**Physical State** powder**Colour** white**Odour** odourless**Solubility** Very soluble in Water, soluble in Chloroform, slightly soluble in Acetone and practically insoluble in Ethyl Ether**Molecular weight** 447,83**Formula** C₂₁H₂₇ClN₂O₂·2HCl**Method No.** 1107/1

DETERMINATIONS	RESULTS	V	LIMITS USP	LIMITS EP	LIMITS COSMA
IDENTIFICATION <i>I.R. spectrum</i> <i>Ultraviolet Absorptivities</i> <i>a230 nm sample</i> <i>a230 nm standard</i> <i>difference</i> <i>Chlorides test</i>	Positive Positive 29,23 29,72 1,65 % Positive		Positive Positive n m t 3,0% Positive	Positive Positive	
Clarity of solution Colour of solution	clear n m t yellow degree 7			Clear n m t yellow degree 7	
Melting point	199,8 °C / 200,3 °C		about 200°C with decomposition	about 200°C with decomposition	
Specific rotation	-0,0040 °			min -0,10° max +0,10°	
Loss on drying	0,14 %		n m t 5,0%	n m t 5,0%	
Residue on ignition	0,002 %		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</i> <i>(on dried substance)</i> <i>HPLC</i> <i>(on dried substance)</i>	99,44 % 100,47 %		min 98,0% max 100,5% min 98,0% max 102,0%	min 99,0% max 101,0%	
Related substances (HPLC) Labelled Impurities <i>IDZ1</i> <i>Deschlorohydroxyzine</i> Other Impurities <i>Dimer</i> <i>Desethoxyhydroxyzine</i> <i>Ethoxyhydroxyzine</i> Unknown Impurity Max Total Impurities	Not quantifiable 0,01 % Not quantifiable Not quantifiable Not detectable 0,02 % 0,07 %		n m t 0,3% n m t 0,3% n m t 1,5%	n m t 0,1% n m t 0,1% n m t 0,3%	n m t 0,1% n m t 0,1% n m t 0,1% n m t 0,10%
RESIDUAL SOLVENTS <i>Acetone</i> <i>Isobutyl Alcohol</i> <i>Methylisobutylketone</i>	1,1 ppm 14,7 ppm 30,5 ppm				n m t 500 ppm n m t 1000 ppm n m t 500 ppm


(Qualified Person)



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Analysis

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PRODOTTO

HYDROXYZINE HYDROCHLORIDE

Product

Physical State powder

Colour white

Odour odourless

Solubility Very soluble in Water, soluble in Chloroform, slightly soluble in Acetone and practically insoluble in Ethyl Ether

Molecular weight 447,83

Formula C₂₁H₂₇ClN₂O₂·2HCl

Method No. 1107/1

DETERMINATIONS	RESULTS	V	LIMITS USP	LIMITS EP	LIMITS COSMA
Bulk density	0,15 g/ml				min 0,15 g/ml max 0,30 g/ml
Tapped density	0,27 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	93,8 %				n l t 50% passes 200 mcm

We hereby certify that the material identified above has been analysed and found in accordance with the specifications of USP and Ph. Eur.

(Qualified Person)