



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 211381

Product:	HYDROXYZINE HYDROCHLORIDE
Lot:	211381
Expiry date:	01/09/2025
Reference:	Cumple PhEur10.3
Synonyms:	
Formula:	C ₂₁ H ₂₇ ClN ₂ O ₂ ·2HCl
Molecular weight:	447,83 g/mol

Assay	Result	Specification	
Assay	99,5 %	99,0-101,0%	
Sulphated ashes	0,02 %	<= 0,1%	=
Loss on drying (1 g, 105°C)	0,41 %	<= 5.0%	
Optical rotation	-0,05°	(-0,10°)-(+0,10°)	=
Related substances (HPLC)	Conform	Test PhEur	=
Heavy metals	<= 10 ppm	<= 10 ppm	
Appearance of the S solution (10% water)	Conform	Test PhEur	=
Melting point (Mettler)	199,3-199,8 °C	Approx. 200°C (dec.)	=
Organoleptic properties	Conform	PhEur	
Residual solvent: Methyl isobutyl ketone	<= 5000 ppm	<= 5000 ppm	#
Identification	Conform (A,D)	Test PhEur (A,D)	
Residual solvent: Isobutanol	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Total impurities	<= 0,3 %	<= 0,3 %	=
Any other impurity	<= 0,1 %	<= 0,1 %	=

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 26/03/2021

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00152 COSMA, S.p.A.

Manufacturer batch: 202100131-110720035

Judgement:
APPROVED

Product	Name	Capacity	Batch
1150722	HIDROXIZINA CLORHIDRATO	5 g	211381-E-1
1150722	HIDROXIZINA CLORHIDRATO	5 g	211381-E-2
1150722	HIDROXIZINA CLORHIDRATO	5 g	211381-E-3

1150723	HIDROXIZINA CLORHIDRATO (INACTIVO)	10 g	211381-F-1
1150723	HIDROXIZINA CLORHIDRATO (INACTIVO)	10 g	211381-F-2
1150724	HIDROXIZINA CLORHIDRATO	25 g	211381-G-1
1150724	HIDROXIZINA CLORHIDRATO	25 g	211381-G-2
1150724	HIDROXIZINA CLORHIDRATO	25 g	211381-G-3
1150724	HIDROXIZINA CLORHIDRATO	25 g	211381-G-4
1150727	HIDROXIZINA CLORHIDRATO (INACTIVO)	250 g	211381-N-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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