



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240501

Product:	HYDROXYZINE HYDROCHLORIDE
Lot:	240501
Expiry date:	23/10/2028
Reference:	Cumple PhEur11.4
Synonyms:	
Formula:	C ₂₁ H ₂₇ ClN ₂ O ₂ ·2HCl
Molecular weight:	447,83 g/mol

Assay	Result	Specification	
Identification	Conform (A,D)	Test PhEur (A,D)	
Organoleptic properties	Conform	PhEur	
Melting point (Mettler)	203 °C	Approx. 200°C (dec.)	
Appearance of the S solution (10% water)	Conform	Test PhEur	
Heavy metals	<= 10 ppm	<= 10 ppm	
Related substances (HPLC)	Conform	Test PhEur	
Optical rotation	(0,00 °)	(-0,10°)-(+0,10°)	
Loss on drying (1 g, 105°C)	0,44 %	<= 5.0%	
Sulphated ashes	0,00 %	<= 0,1%	
Assay	99,4 %	99,0-101,0%	
Any other impurity	< 0,03 %	<= 0,1 %	
Total impurities	< 0,03 %	<= 0,3 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Isobutanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methyl isobutyl ketone	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 29/04/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00152 COSMA, S.p.A.

Manufacturer batch: 202400105-110723059

Product	Name	Capacity	Batch
1150722	HIDROXIZINA CLORHIDRATO (INACTIVO)	5 g	240501-E-1
1150722	HIDROXIZINA CLORHIDRATO (INACTIVO)	5 g	240501-E-2
1150722	HIDROXIZINA CLORHIDRATO (INACTIVO)	5 g	240501-E-3

1150724	HIDROXIZINA CLORHIDRATO	25 g	240501-G-1
1150724	HIDROXIZINA CLORHIDRATO	25 g	240501-G-2
1150724	HIDROXIZINA CLORHIDRATO	25 g	240501-G-3
1150724	HIDROXIZINA CLORHIDRATO	25 g	240501-G-4

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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