



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241104

Product:	
Lot:	241104
Expiry date:	23/05/2028
Reference:	Cumple PhEur11.4
Synonyms:	
Formula:	C ₁₆ H ₂₄ N ₂ O·HCl
Molecular weight:	296,8 g/mol

Assay	Result	Specification	
Organoleptic properties	Conform	PhEur	
Identification	Conform (A,D)	Test PhEur (A,D)	
Acidity or alkalinity	Conform		
Appearance of solution	Conform	Test PhEur	
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Impurity A	ND	<= 0,15 %	
Elemental impurities	Conform	Test PhEur	#
Total impurities	< 0,05 %	<= 0,5 %	
Water	0,09 %	<= 0,3 %	
Related substances (HPLC)	Conform	Test PhEur	
Assay	100,3 %	99,0 - 101,0 %	
Sulphated ashes	0,03 %	<= 0,1 %	

Organoleptic characteristics:

Conservation:

Date of analysis: 13/06/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMIKALIEN MINDEN GmbH

Manufacturer batch: 23212090

Product	Name	Capacity	Batch
1100168	OXIMETAZOLINA CLORHIDRATO	1 g	241104-D-1
1100169	OXIMETAZOLINA CLORHIDRATO	5 g	241104-E-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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