



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252013

Product:	GLYCOPYRROLATE
Lot:	252013
Expiry date:	31/12/2027
Reference:	Cumple PhEur12.1
Synonyms:	Glicopirronio bromuro.
Formula:	C ₁₉ H ₂₈ BrNO ₃
Molecular weight:	398.34 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		
Acidity or alkalinity	Conform	Test PhEur	
Loss on drying	0,05 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
Related substances (HPLC)	Conform	Test PhEur	
Impurity N	0,13 %	<= 0,2%	
Assay	99,3 %	99,0-101,0%	
Impurity E	< 0,05 %	<= 0,2 %	
Impurity I	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,5 %	
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Heptane	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Acetonitrile	< 410 ppm	<= 410 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Benzene	< 2 ppm	<= 2 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual Solvent: O-Xilene	< 196 ppm	<= 196 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methyl ethyl ketone	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform		#

Organoleptic characteristics: White or almost white crystalline powder. Freely soluble in water, soluble in ethanol 96%, very slightly soluble in methylene chloride

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 11/03/2026

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00340 SWATI SPENLOSE PRIVATE LIMITED (UNIT-I)

Manufacturer batch: GLP-125001

Product	Name	Capacity	Batch
1112000	GLICOPIRROLATO	1 g	252013-D-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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