

**BROMURO DE GLICOPIRRONIO (GLICOPIRROLATO) (EUR. PH.)**

PRODUCT CODE: 151419		CAS Nº: 51186-83-5	ANALYSIS Nº: 332/24
MANUFACTURER BATCH:	103623004	CERTIFICATE ID:	44.581
SUPPLIER BATCH:	2411081.1843	MANUFACTURING DATE:	09/05/2023
METAPH BATCH:	0191224	EXPIRY DATE:	09/05/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Freely soluble in water, soluble in ethanol (96 per cent), very slightly soluble in methylen chloride	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Acidity or alcalinity	Red or orange solution	Complies
Impurity N	<= 0.2 %	< 0.025 % (*)
Related substances		
Impurity I	<= 0.3 %	< 0.05 %
Impurity E	<= 0.2 %	< 0.05 %
Unspecified impurities	<= 0.10 %	< 0.05 %
Total impurities	<= 0.5 %	< 0.05 %
Loss on drying	<= 0.5 %	0.1 %
Sulfated ash	<= 0.1 %	0.08 %
Assay	99.0 - 101.0 %	100.4 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Glycopyrronium Bromide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(\*) Data adapted from the supplier's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

**STORAGE**

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

Analysis date: 03/02/2025  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000767  
AMSA S.P.A. (ANONIMA MATERIE SINTETICHE &  
AFFINI S.P.A.)  
Via Olgettina, 25  
20132 MILÁN