



## TECHNICAL DATA SHEET

151419-TDS-ENG-2023

<b>BROMURO DE GLICOPIRRONIO (GLICOPIRROLATO)</b>		
DESCRIPTION DCI: BROMURO DE GLICOPIRRONIO		DESCRIPTION DOE: GLYCOPYRRONIUM BROMIDE
CAS Nº: 51186-83-5	EC Nº: 209-887-0	AEMPS CODE: ---
MOL. WEIGHT: 398.33	MOL. FORMULA: C19H28BrNO3	ARTICLE CODE: 151419

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

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

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

### REMARKS

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".

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.