

BETANECOL CLORURO (USP)

PRODUCT CODE: 002794	CAS Nº: 590-63-6	ANALYSIS Nº: 142/25
MANUFACTURER BATCH: FP/BC/005/07/24	CERTIFICATE ID: 46.605	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/07/2024	
METAPH BATCH: 0290525	EXPIRY DATE: 30/06/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White crystalline powder	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Assay	98.0 - 101.5 %	99.3 %
Residue on ignition	=< 0.1 %	0.07 %
Organic volatile impurities		
Desacetyl Methacholine	=< 1.0 %	Not Detected
Unspecified impurities	=< 0.1 %	Not Detected
Total impurities	=< 1.5 %	Not Detected
pH	5.5 - 6.5	6.1
Loss on drying	=< 1.0 %	0.04 %

COMPLIES WITH

USP 2025

REMARKS

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

Bethanechol Chloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

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 tightly closed containers, in a dry and well ventilated place.

Analysis date: 30/07/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Not compliant
 Original certificate available upon request

Manufacturer: 40001017
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