

BETANECOL CLORURO (USP)

PRODUCT CODE: 002794	CAS Nº: 590-63-6	ANALYSIS Nº: 208/23
MANUFACTURER BATCH: BTHA-168	CERTIFICATE ID: 39.167	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 31/05/2023	
METAPH BATCH: 0150723	RETEST DATE: 31/05/2025	

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 %	100.8 %
Residue on ignition	=< 0.1 %	< 0.01 % (*)
Organic volatile impurities		(*)
Desacetyl Methacholine	=< 1.0 %	Not Detected
Unspecified impurities	=< 0.1 %	Not Detected
Total impurities	=< 1.5 %	< 0.01 %
pH	5.5 - 6.5	5.7 (*)
Loss on drying	=< 1.0 %	0.3 %

COMPLIES WITH

USP 2023

REMARKS

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

(*) Data adapted from the manufacturer'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 tightly closed containers, in a dry and well ventilated place.

Analysis date: 18/09/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000771
 SERATEC S.A.S.
 2, RUE DU THYMERAIIS I
 28190 COURVILLE SUR EURE
 (FRANCE)

