



TECHNICAL DATA SHEET

002794-TDS-ENG-2025

BETANECOL CLORURO (USP)		
DESCRIPTION DCI: BETHANECHOL CHLORIDE		DESCRIPTION DOE: BETANECOL CLORURO
CAS Nº: 590-63-6	EC Nº: 209-686-8	AEMPS CODE: 3446CL
MOL. WEIGHT: 196.68	MOL. FORMULA: C7H17ClN2O2	ARTICLE CODE: 002794

ATTRIBUTES	SHOULD BE
Appearance	White crystalline powder
Identification A	Complies
Identification B	Complies
Identification C	Complies
Assay	98.0 - 101.5 %
Residue on ignition	=< 0.1 %
Organic volatile impurities	
Desacetyl Methacholine	=< 1.0 %
Unspecified impurities	=< 0.1 %
Total impurities	=< 1.5 %
pH	5.5 - 6.5
Loss on drying	=< 1.0 %

COMPLIES WITH

USP 2025

STORAGE

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

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.

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.

Properties

BETANECOL CHLORIDE, a choline ester, is a quaternary ammonium parasympathomimetic, which mainly has the muscarinic actions of acetylcholine. It is not metabolized by cholinesterases; therefore, its effects are more lasting than those of acetylcholine.

BETANECOL CHLORIDE has little or no nicotinic activity and is used for its actions on the bladder and digestive system.

Pharmacokinetics

BETANECOL CHLORIDE is poorly absorbed in the digestive tract. It is not hydrolyzed by cholinesterases. BETANECOL CHLORIDE, at standard doses, does not cross the blood-brain barrier.

Applications

All methods are validated by the official pharmacopoeias and/or by the authorized manufacturer

A080.02.ENG



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It has been used as an alternative to catheterization in the treatment of urinary retention and also in gastric atony and retention, abdominal distension after surgery, congenital megacolon and in gastroesophageal reflux. It is also used in ophthalmology.

Dosage

Oral route (adults). Initially 5 - 10 mg followed by increments of 5 mg every hour until a satisfactory response is achieved. The maintenance dose is 5-50 mg, 2-4 times a day.

The oral pediatric dose is 200 µg / Kg weight / 3 times per day.

Subcutaneous route (adults). Initially 2.5 mg every 15-30 minutes, up to 10 mg to obtain a satisfactory response, then 2.5-10 mg to obtain a satisfactory response, then 2.5-10 mg, 3-4 times per day.

Subcutaneous (pediatric). Dosage of 150 - 200 µg / Kg weight / 3 times per day.

Topical route, in the conjunctival sac, as a 1% solution.

Sterilization

BETANECOL CHLORIDE solutions can be disinfected by autoclaving at 120 °C for 20 minutes without losing color or losing power.

Precautions

It should not be administered intravenously or intramuscularly because it is likely that very serious muscarinic side effects will appear, in which case atropine should be administered as a matter of urgency. Systemic adverse effects may occur even after subcutaneous administration.