

BETANECOL CLORURO (USP)

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|------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 002794 | CAS Nº: 590-63-6 | ANALYSIS Nº: 011/24 |
| MANUFACTURER BATCH: BTHA-175 | CERTIFICATE ID: 40.816 | |
| SUPPLIER BATCH: ---- | MANUFACTURING DATE: 01/12/2023 | |
| METAPH BATCH: 0100124 | RETEST DATE: 30/11/2025 | |

| 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 % | 100.2 % |
| Residue on ignition | =< 0.1 % | 0.02 % |
| Organic volatile impurities | | |
| Desacetyl Methacholine | =< 1.0 % | Not Detected |
| Unspecified impurities | =< 0.1 % | < 0.01 % |
| Total impurities | =< 1.5 % | < 0.01 % |
| pH | 5.5 - 6.5 | 5.9 |
| Loss on drying | =< 1.0 % | 0.2 % |

COMPLIES WITH

USP 2024

REMARKS

All data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 12/03/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000771
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