

# METAPHARMACEUTICAL

N DE LOTE:

0290525

20/08/2023



## CERTIFICATE OF ANALYSIS

### PRODUCT : BETHANECHOL CHLORIDE USP

Batch No. : FP/BC/005/07/24 Mfg Date : July 2024 Exp. Date : June 2029	Molecular Formula : $C_7H_{17}ClN_2O_2$ Molecular weight : 196.67 CAS No : [ 590-63 -6 ]	A. R. No. : FP/BC/005/24/USP Batch Size : 16.050 Kg Date Of Release : 12/08/2024
TEST	SPECIFICATION	OBSERVATION
1) Description	Colorless or white crystals or white, crystalline powder, usually having a slight, amine like odor. Exhibits polymorphism, and of two crystalline forms observed, one melts at about 211°C and the other melts at about 219°C. Is hygroscopic. May form lumps during storage*	White crystalline powder, having a slight amine like odor. Melts about 217.0°C  Is hygroscopic. May form lumps during storage.
2) Solubility	Freely soluble in water, and in alcohol; Insoluble in chloroform and in Ether.	Complies
3) Identification: A: IR-spectrum B: Identification By IC  C. Chloride test	IR concordant with working Standard. The Retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution as obtained in the assay. Meets the requirements.	Complies The Retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution as obtained in the assay. Complies
4) Assay by IC (On dried basis)	NLT 98.0 % and NMT 101.5%	99.88 %
5) Residue on ignition	NMT 0.1 % w/w	0.06 % w/w
6) Related Compound by IC 2-hydroxypropyltrimethyl ammonium chloride Any other individual impurity Total impurities	NMT 1.0%  NMT 0.10% NMT 1.5%	Not Detected  Not Detected Not Detected
7) pH (1% Solution in Water)	Between 5.5 and 6.5	5.86
8) Loss on drying at 105 °C(For 2Hrs)	NMT 1.0 % w/w	0.34 % w/w
9) Residual solvents Isopropyl alcohol Chloroform Benzene Toluene	NMT 5000 ppm NMT 60 ppm NMT 2 ppm NMT 890 ppm	105 ppm 4 ppm Not Detected 1 ppm

**REMARKS :** The above tested Batch No.: FP/BC/005/07/24 confirms on all respect to Bethanechol Chloride USP Specification.

Prepared by: P.V. Gubav Designation : Officer/Sr. Executive Q.C. Sign : Date : 12/08/2024	Checked by: Vijay Dhume Designation : Manager Q.C. Sign : Date : 12/08/2024	Approved by: Jagadule S.B Designation : Manager Q.A. Sign : Date : 12/08/2024
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Format No.: SOP/QC/75/F1-R0

\*Milling and sifting can be performed if lumps observed there is no impact on quality attributes.

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