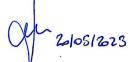
METAPHARMACEUTICAL

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	CERTIFICATE OF ANALYSIS	
	UCT: BETHANECHOL CHLORID	
Batch No .: FP/BC/005/07/24	Molecular Formula: C ₇ H ₁₇ Cl N ₂ O ₂	A. R. No.: FP/BC/005/24/USP
Mfg Date: July 2024	Molecular weight : 196.67	Batch Size: 16.050 Kg
Exp. Date: June 2029	CAS No : [590-63 -6]	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	IR concordant with working Standard.	Complies
B: Identification	The Retention time of the major peak in	The Retention time of the major peal
Ву ІС	the chromatogram of the sample solution	in the chromatogram of the sample
	corresponds to that in the chromatogram	solution corresponds to that in the
	of the standard solution as obtained in the	chromatogram of the standard
	assay.	solution as obtained in the assay.
C. Chloride test	Meets the requirements.	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
Related Compound by IC 2-hydroxypropyltrimethyl ammonium chloride	NMT 1.0%	Not Detected
Any other individual impurity	NMT 0.10%	Not Detected
Total impurities	NMT 1.5%	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	NMT 5000 ppm	105 ppm
Chloroform	NMT 60 ppm	4 ppm
Benzene	NMT 2 ppm	Not Detected
Toluene	NMT 890 ppm	1 ppm
REMARKS: The above tested Batch USP Specification.	No.: FP/BC/005/07/24 confirms on all response	ect to Bethanechol Chloride
Prepared by: P.N. Gurar	Checked by: Myay Dhuma	Approved by: Jagadule 5-13
Designation : Officer/Sr. Executive Q.	C. Designation: Manager Q.C.	Designation : Manager Q.A.
	Sign M: V1	Sign : Tayudule
Sign :		

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

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