DISHMAN CARBOGEN AMCIS LIMITED
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Certificate of Analysis

PRODUCT	BENZETHONIUM CHLORIDE USP	REF.	NDQC-SP80-BAI-07
BATCH NO.		MFG DATE	November – 2019
BATCH SIZE	1261.90 kg	RETEST DATE	October – 2022
INSP LOT NO.		REISSUED DATE	04.05.2020

SR. NO.	TEST	RESULT	METHOD REFERENCE	SPECIFICATION
1.0	Description	White crystals, having a mild odor. Its solution (1 in 100) is slightly alkaline to litmus.	<USP>	White crystals, having a mild odor. Its solution (1 in 100) is slightly alkaline to litmus.
2.0	Solubility	Soluble in water, in alcohol and in chloroform; slightly soluble in ether.	<USP>	Soluble in water, in alcohol and in chloroform; slightly soluble in ether.
3.0	Identification			
	A. Chloride	Complies	<USP>	A white precipitate, which is insoluble in 2N nitric acid but soluble in 6 N ammonium hydroxide is formed.
	B. Infrared absorption	Complies	<USP 197 K>	The infrared spectrum of the test sample should be concordant with the infrared spectrum of working reference standard.
	C. Liquid Chromatography	Complies	<USP (621)>	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
4.0	Assay (on dried basis) (by HPLC)	99.7	<USP (621)>	Not less than 97.0 % w/w and Not more than 103.0 % w/w
5.0	Impurities			
	5.1 Residue on ignition	0.07	<USP (281)>	Not more than 0.1 % w/w
	5.2 Organic impurities → Total impurities	0.39	<USP (621)>	Not more than 1.0 %
6.0	Specific tests			
	6.1 Loss on drying (at 105 °C, for 4 hours.)	2.90	<USP (731)>	Not more than 5.0 % w/w
	Additional test			
7.0	Residual solvents			
	1.) Methyl Ethyl Ketone	BDL	AMV R-BAI-01/IV	Not more than 5000 ppm
	2.) Toluene	BDL		Not more than 890 ppm

Remark : The material conform to the above specification.

Prepared by/Date:	Reviewed by/Date:	Approved by/Date:
Pradip Sabat (Officer–QC)	Shailesh Kachhia (Sr. Manager–QC)	Kaushik Patel (AGM–QC)

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PRODUCT	**BENZETHONIUM CHLORIDE USP**	**REF.**	**NDQC-SP80-BAI-07**
BATCH NO.		**MFG DATE**	**December – 2019**
BATCH SIZE	**1339.90 kg**	**RETEST DATE**	**November – 2022**
INSP LOT NO.		**REISSUED DATE**	**04.05.2020**

SR. NO.	TEST	RESULT	METHOD REFERENCE	SPECIFICATION
1.0	Description	White crystals, having a mild odor. Its solution (1 in 100) is slightly alkaline to litmus.	<USP>	White crystals, having a mild odor. Its solution (1 in 100) is slightly alkaline to litmus.
2.0	Solubility	Soluble in water, in alcohol and in chloroform; slightly soluble in ether.	<USP>	Soluble in water, in alcohol and in chloroform; slightly soluble in ether.
3.0	Identification			
	A. Chloride	Complies	<USP>	A white precipitate, which is insoluble in 2N nitric acid but soluble in 6 N ammonium hydroxide is formed.
	B. Infrared absorption	Complies	<USP 197 K>	The infrared spectrum of the test sample should be concordant with the infrared spectrum of working reference standard.
	C. Liquid Chromatography	Complies	<USP (621)>	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
4.0	Assay (on dried basis) (by HPLC)	99.8	<USP (621)>	Not less than 97.0 % w/w and Not more than 103.0 % w/w
5.0	Impurities			
	5.1 Residue on ignition	0.07	<USP (281)>	Not more than 0.1 % w/w
	5.2 Organic impurities		<USP (621)>	
	→ Total impurities	0.15		Not more than 1.0 %
6.0	Specific tests			
	6.1 Loss on drying (at 105 °C, for 4 hours.)	2.95	<USP (731)>	Not more than 5.0 % w/w
	Additional test			
7.0	Residual solvents			
	1.) Methyl Ethyl Ketone	BDL	AMV R-BAI-01/IV	Not more than 5000 ppm
	2.) Toluene	BDL		Not more than 890 ppm

Remark : The material conform to the above specification.

04/05/20

Prepared by/Date:
Pradip Sabat
(Officer–QC)

04/05/20

Reviewed by/Date:
Shailesh Kachhia
(Sr. Manager–QC)

04/05/20

Approved by/Date:
Kaushik Patel
(AGM–QC)

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PRODUCT	**BENZETHONIUM CHLORIDE USP**	**REF.**	**NDQC-SP80-BAI-07**
BATCH NO.		**MFG DATE**	**August – 2019**
BATCH SIZE	**1191.35 kg**	**RETEST DATE**	**July – 2022**
INSP LOT NO.		**REISSUED DATE**	**11.02.2020**

SR. NO.	TEST	RESULT	METHOD REFERENCE	SPECIFICATION
1.0	Description	White crystals, having a mild odor. Its solution (1 in 100) is slightly alkaline to litmus.	<USP>	White crystals, having a mild odor. Its solution (1 in 100) is slightly alkaline to litmus.
2.0	Solubility	Soluble in water, in alcohol and in chloroform; slightly soluble in ether.	<USP>	Soluble in water, in alcohol and in chloroform; slightly soluble in ether.
3.0	Identification			
	A. Chloride	Complies	<USP>	A white precipitate, which is insoluble in 2N nitric acid but soluble in 6 N ammonium hydroxide is formed.
	B. Infrared absorption	Complies	<USP 197 K>	The infrared spectrum of the test sample should be concordant with the infrared spectrum of working reference standard.
	C. Liquid Chromatography	Complies	<USP (621)>	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
4.0	Assay (on dried basis) (by HPLC)	99.5	<USP (621)>	Not less than 97.0 % w/w and Not more than 103.0 % w/w
5.0	Impurities			
	5.1 Residue on ignition	0.08	<USP (281)>	Not more than 0.1 % w/w
	5.2 Organic impurities		<USP (621)>	
	→ Total impurities	0.79		Not more than 1.0 %
6.0	Specific tests			
	6.1 Loss on drying (at 105 °C, for 4 hours.)	2.67	<USP (731)>	Not more than 5.0 % w/w
	Additional test			
7.0	Residual solvents			
	1.) Methyl Ethyl Ketone	BDL	AMV R-BAI-01/IV	Not more than 5000 ppm
	2.) Toluene	BQL		Not more than 890 ppm

Remark : The material conform to the above specification.

11/02/20
Prepared by/Date:
Yogesh Rajput
(Executive–QC)

11/02/20
Reviewed by/Date:
Shailesh Kachhia
(Sr. Manager–QC)

11/02/20
Approved by/Date:
Kaushik Patel
(AGM–QC)