Lot. 0160619

SCL

Saurav Chemicals Limited

Corporate Office: Plot No. 370, Industrial Area, Phase-II Panchkula-134109, (Haryana) INDIA

CERTIFICATE OF ANALYSIS
ATROPINE SULFATE Ph. Eur.

Batch No.	ATS180006	**Mfg. Date**	August- 2018
Batch Qty.	13.20 Kg	**Retest Date**	July - 2021
A.R. No.	ATSD180006	**Date of analysis**	12-Sep-18

TESTS	RESULTS	SPECIFICATIONS
1.0 Description	White Crystalline powder.	White or almost white crystalline powder or colourless crystals.
2.0 Solubility	Very soluble in water, freely soluble in ethanol (96%).	Very soluble in water, freely soluble in ethanol (96%).
3.0 Identification		
3.1 Optical rotation(°)	-0.07	Between -0.50 to +0.05
3.2 By IR	The IR absorption spectrum of sample is match with the reference spectrum of the Atropine sulfate monohydrate working standard.	The IR absorption spectrum of sample should match with the reference spectrum of the Atropine sulfate monohydrate working standard.
3.3 Test for sulfates	A white precipitate is produced.	A white precipitate should be produced.
4.0 pH	5.79	Between 4.5 to 6.2
5.0 Water(By Karl Fischer) (%w/w)	2.3	Between 2.0 to 4.0
6.0 Sulfated ash (% w/w)	0.06	Not more than 0.1
7.0 Assay (Potentiometrically on anhydrous basis)(% w/w)	99.5	Between 99.0 to 101.0

Prepared By / Date	Checked By / Date	Approved By / Date
15-may-19	15-May-19	15-May-19

Mfd. By: Saurav Chemicals Limited, Village Bhagwanpura, Barwala Road, Dera Bassi, District Ajitgarh/S.A.S. Nagar (Mohali), Punjab, India.

QUALITY ASSURANCE RELEASE * SCL * Sign. Date 30-May-19

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TESTS	RESULTS	SPECIFICATIONS
8.0 Related Substance (by HPLC) (%)		
8.1 Impurity A	Not detected	Not more than 0.2
8.2 Impurity B	Not detected	Not more than 0.2
8.3 Impurity C	Not detected	Not more than 0.2
8.4 Impurity D	Not detected	Not more than 0.2
8.5 Impurity E	Not detected	Not more than 0.3
8.6 Impurity F	Not detected	Not more than 0.2
8.7 Impurity G	Not detected	Not more than 0.2
8.8 Impurity H	Not detected	Not more than 0.3
8.9 Unspecified impurity	BDL	Not more than 0.10
8.10 Total impurities	BDL	Not more than 0.5
9.0 Residual solvents (By GC-HS) (ppm)		
9.1 Dichloromethane	Not detected	Not more than 600
9.2 Isopropyl alcohol	458	Not more than 5000
9.3 Acetonitrile	BDL	Not more than 410
9.4 Acetone	Not detected	Not more than 5000
Additional test		
10.0 Microbiological tests (cfu / gm)		
10.1 Total aerobic microbial count	13	Not more than 1000
10.2 Total yeasts and moulds count	Less than 1	Not more than 100
11.0 Endotoxin test (EU/mg)	Less than 0.25	Not more than 55.60

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QUALITY ASSURANCE Sign. Date 30-May-19 SCL

SCL

Saurav Chemicals Limited

Corporate Office: Plot No. 370, Industrial Area, Phase-II Panchkula-134109, (Haryana) INDIA

CERTIFICATE OF ANALYSIS
ATROPINE SULFATE Ph. Eur.

Batch No.	ATS180006	**Mfg. Date**	August- 2018
Batch Qty.	13.20 Kg	**Retest Date**	July - 2021
A.R. No.	ATSD180006	**Date of analysis**	12-Sep-18

TESTS	RESULTS	SPECIFICATIONS
12.0 Pathogen analysis		
Escherichia coli	Absent	Should be absent
Staphylococcus aureus	Absent	Should be absent
Pseudomonas species	Absent	Should be absent
Salmonella species	Absent	Should be absent
Clostridium species	Absent	Should be absent

Report: The product complies with respect to Ph.Eur. Specification.

15-May-19	15-May-19	15-May-19
Prepared By / Date	Checked By / Date	Approved By / Date

Name of impurities
Impurity A = Apoatropine
Impurity B = Noratropine
Impurity C = Tropic acid
Impurity D = 6-hydroxyhyoscyamine
Impurity E = 7- hydroxyhyoscyamine
Impurity F = Hyoscine
Impurity G = Littorine
Impurity H = Not mentioned in EP (Unknown structure)

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QUALITY ASSURANCE RELEASE * SCL * Sign. Date 30 May 19