

Saurav Chemicals Limited

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

	(1111)	min, 11 12 11 1	
	CERTIFICAT	TE OF ANALYSIS	
	ATROPINE S	ULFATE 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
		Q-1:

Prepared By / Date Checked By / Date Approved By / Date

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

Page 1 of 3



Saurav Chemicals Limited

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

	CERTIFICA	TE 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

RESULTS 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 8.4 Impurity D Not detected Not more than 0.2 8.5 Impurity E Not detected Not more than 0.2 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 0.2 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 9.3 Acetonitrile BDL Not more than 5000 Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial 13 Not more than 1000		779777	T
(by HPLC) (%) 8.1 Impurity A 8.2 Impurity B Not detected Not more than 0.2 8.3 Impurity C 8.4 Impurity D Not detected Not more than 0.2 8.5 Impurity E Not detected Not more than 0.2 8.6 Impurity F Not detected Not more than 0.2 8.7 Impurity G 8.8 Impurity H Not detected Not more than 0.2 8.9 Unspecified impurity BDL 8.10 Total impurities BDL 9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial Not detected Not more than 0.2 Not more than 0.10 Not more than 600 Not more than 5000 Not more than 5000 Not more than 5000 Not more than 5000	TESTS	RESULTS	SPECIFICATIONS
8.1 Impurity A 8.2 Impurity B Not detected Not more than 0.2 Not more than 0.3 Not more than 0.3 Not more than 0.3 Not more than 0.2 Not more than 0.2 Not more than 0.2 Not more than 0.2 Not more than 0.3 Not more than 0.3 Not more than 0.3 Not more than 0.10 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 5000 Not more than 5000 Not more than 5000 Not more than 1000	8.0 Related Substance		
8.2 Impurity B 8.3 Impurity C Not detected Not more than 0.2 Not more than 0.3 Not more than 0.2 Not more than 0.3 Not more than 0.3 Not more than 0.3 Not more than 0.10 Not more than 0.10 Not more than 0.5 9.0 Residual solvents (By GC-HS) (ppm) 9.1 Dichloromethane Not detected Not more than 600 Not more than 5000 Not more than 5000 Not more than 410 Not more than 5000 Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial	(by HPLC) (%)	*	
8.3 Impurity C 8.4 Impurity D Not detected Not more than 0.2 8.5 Impurity E Not detected Not more than 0.2 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 0.2 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 9.2 Isopropyl alcohol 9.3 Acetonitrile BDL Not more than 600 Not more than 5000 Not more than 5000 Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial Not detected Not more than 5000 Not more than 5000 Not more than 5000	8.1 Impurity A	Not detected	Not more than 0.2
8.4 Impurity D 8.5 Impurity E Not detected Not more than 0.2 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 0.2 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 9.3 Acetonitrile BDL Not more than 5000 Not more than 410 Not more than 5000 Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial 13 Not more than 1000	8.2 Impurity B	Not detected	Not more than 0.2
8.5 Impurity E 8.6 Impurity F Not detected Not more than 0.3 Not more than 0.2 Not more than 0.3 Not more than 0.5 Not more than 0.10 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 9.3 Acetonitrile BDL Not more than 5000 Not more than 410 Not more than 5000 Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial	8.3 Impurity C	Not detected	Not more than 0.2
8.6 Impurity F 8.7 Impurity G 8.8 Impurity H Not detected Not more than 0.2 Not more than 0.2 Not more than 0.2 Not more than 0.2 Not more than 0.3 Not more than 0.3 Not more than 0.10 Not more than 0.10 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.10 Not more than 0.5 Not more than 0.10 Not more than 0.10 Not more than 0.5 Not more than 0.10 Not more than 5000 Not more than 5000 Not more than 5000 Not more than 1000 Not more than 1000	8.4 Impurity D	Not detected	Not more than 0.2
8.7 Impurity G 8.8 Impurity H 8.9 Unspecified impurity 8.10 Total impurities 9.0 Residual solvents (By GC-HS) (ppm) 9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial Not detected Not more than 0.2 Not more than 0.3 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 4.0 Not more than 5000 Not more than 5000 Not more than 5000 Not more than 5000	8.5 Impurity E	Not detected	Not more than 0.3
8.8 Impurity H 8.9 Unspecified impurity 8.10 Total impurities 9.0 Residual solvents (By GC-HS) (ppm) 9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial Not detected Not more than 0.3 Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 4.0 Not more than 5000 Not more than 5000 Not more than 5000 Not more than 5000	8.6 Impurity F	Not detected	Not more than 0.2
8.9 Unspecified impurity 8.10 Total impurities 9.0 Residual solvents (By GC-HS) (ppm) 9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial BDL Not more than 0.10 Not more than 0.5 Not more than 0.5 Not more than 40.5 Not more than 5000 Not more than 410 Not more than 5000 Not more than 1000	8.7 Impurity G	Not detected	Not more than 0.2
8.10 Total impurities 9.0 Residual solvents (By GC-HS) (ppm) 9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial BDL Not more than 0.5 Not more than 600 Not more than 5000 Not more than 410 Not more than 5000 Not more than 1000	8.8 Impurity H	Not detected	Not more than 0.3
9.0 Residual solvents (By GC-HS) (ppm) 9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu/gm) 10.1 Total aerobic microbial	8.9 Unspecified impurity	BDL	Not more than 0.10
(By GC-HS) (ppm) 9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial Not detected Not more than 600 Not more than 5000 Not more than 410 Not more than 5000 Not more than 1000	8.10 Total impurities	BDL	Not more than 0.5
9.1 Dichloromethane 9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial Not detected Hot detected Not more than 5000 Not more than 5000 Not more than 5000 Not more than 1000	9.0 Residual solvents		
9.2 Isopropyl alcohol 9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial 458 Not more than 5000 Not more than 5000 Not more than 5000 Not more than 1000	(By GC-HS) (ppm)	- ,	
9.3 Acetonitrile 9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial BDL Not more than 410 Not more than 5000 Not more than 1000	9.1 Dichloromethane	Not detected	Not more than 600
9.4 Acetone Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial Not detected Not more than 5000 Not more than 1000	9.2 Isopropyl alcohol	458	Not more than 5000
Additional test 10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial 13 Not more than 1000	9.3 Acetonitrile	BDL	Not more than 410
10.0 Microbiological tests (cfu / gm) 10.1 Total aerobic microbial 13 Not more than 1000	9.4 Acetone	Not detected	Not more than 5000
(cfu / gm) 10.1 Total aerobic microbial 13 Not more than 1000	Additional test		
10.1 Total aerobic microbial 13 Not more than 1000	10.0 Microbiological tests		
10.1 10.11 10.11 10.10 11.11	(cfu/gm)	v.	a
count	10.1 Total aerobic microbial	13	Not more than 1000
	count	, , , , , , , , , , , , , , , , , , ,	
10.2 Total yeasts and moulds Less than 1 Not more than 100	10.2 Total yeasts and moulds	Less than 1	Not more than 100
count	count	, , , , , , , , , , , , , , , , , , ,	
11.0 Endotoxin test (EU/mg) Less than 0.25 Not more than 55.60	11.0 Endotoxin test (EU/mg)	Less than 0.25	Not more than 55.60
		,	

Checked By / Date Prepared By / Date Approved By / Date

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

Page 2 of 3



Saurav Chemicals Limited

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

***	CERTIFICA	TE 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 analy Escherichia coli Staphylococcus aure Pseudomonas specie Salmonella species Clostridium species	us	Absent Absent Absent Absent Absent		Should be Should be Should be Should be	absent absent absent	
Report: The product	complies with	respect to Ph.Eu	r. Specifica	ation. $\langle \rangle$	TEN 10	
Prepared By	イペタ / Date	Checked By	19 / Date	Appr	oved 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)

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

Page 3 of 3