



ALKALOIDS PRIVATE LIMITED (Unit-I)

Manufacturing Site: 25/3, Gundlapochampally, Medchal-Malkajgiri District, Telangana - 500100, INDIA

Ph No: +91-40-23792010

CERTIFICATE OF ANALYSIS

Product Name	: Hyoscine Butylbromide (CAS No :149-64-4)	Reference	: Ph.Eur.
Batch No.	: 2510122	Quantity	: 1.500 Kg
A.R.No.	: QC/FG/004/22	Date of Analysis	: 10/01/2022
Date of Manufacturing	: Jan-2022	Date of Expiry	: Sep-2026

S.NO.	PARAMETERS	SPECIFICATIONS	RESULT
1.	Appearance	A white or almost white crystalline powder	Complies
2.	Solubility	Freely soluble in <i>water</i> and <i>methylene chloride</i> ; sparingly soluble in anhydrous <i>ethanol</i>	Complies
3.	Identification		
	A) By specific optical rotation (5% w/v solution in water)	A) Should be -18.00° to -20.00°	-19.67°
	B) By Melting Point	B) Should be 139.0°C-141.0°C	139.4°C
	C) By IR method	C) The I.R Spectrum of the sample must be concordant with that of <i>Reference Standard / Working Standard</i>	Complies
	D) By chemical Test as per Ph.Eur.	D) A violet color should develop	Complies
	E) By chemical Test as per Ph.Eur.	E) No precipitate should form	Complies
	F) By test of Bromides	F) Should be positive	Complies
4.	Appearance of Solution	Should be clear and colorless	Complies
5.	Acidity or alkalinity	NMT 0.5mL of 0.01M Hydrochloric acid is required to change the color of indicator to reddish-violet	0.25 mL
6.	Specific Optical Rotation	Should be -18.00° to -20.00°	-19.67°
7.	Loss on Drying	NMT 2.50 % w/w	0.30%
8.	Sulphated Ash	NMT 0.10 % w/w	0.04%
9.	Assay (By Silver Nitrate Titration)	NLT 98.00 % & NMT101.00% Calculated on dry basis	99.89%
10.	Related Substances (By UHPLC)	Impurity A: NMT 0.15 %	Below Disregard Limit
		Impurity B: NMT 0.10 %	Below Disregard Limit
		Impurity C: NMT 0.10 %	0.05%
		Impurity D: NMT 0.10 %	Below Disregard Limit
		Impurity E: NMT 0.10 %	Below Disregard Limit
		Impurity F: NMT 0.10 %	Below Disregard Limit
		Impurity G: NMT 0.10 %	Below Disregard Limit
		Impurity H: NMT 0.10 %	Below Disregard Limit
		Any Other Impurity: NMT 0.10 %	Below Disregard Limit
		Total Impurities: NMT 0.40 %	0.05%



ALKALOIDS PRIVATE LIMITED (Unit-D)

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CERTIFICATE OF ANALYSIS

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S.NO.	PARAMETERS	SPECIFICATIONS	RESULT
Additional Tests (In-House Specifications)			
11.	Residual Solvents (by GC-HS)	a) Methanol: NMT 500 ppm	63 ppm
		b) Acetonitrile: NMT 40 ppm	Below Detection Limit
		c) Methylene Dichloride : NMT 60 ppm	Below Detection Limit
		d) n-Butyl bromide: NMT 15 ppm	7 ppm
12.	Microbial Limits	a) Total Microbial Count: NMT 25 cfu/g	10 cfu/g
		b) Yeast & Mould Count: NMT 25 cfu/g	< 10 cfu/g
		c) Pathogens	
		i) E.coli: Should be Absent	Absent
		ii) Salmonellae: Should be Absent	Absent
		iii) Pseudomonas aeruginosa: Should be Absent	Absent
		iv) Staphylococcus aureus: Should be Absent	Absent
13.	Bacterial Endotoxin (Gel Clot Method)	v) Enterobacteria: Should be Absent	Absent
		NMT 0.25 EU/mg	< 0.25EU/mg

REMARKS: - The product conforms / does not conform to Ph.Eur. specifications.

Drug License No.: 141/RR/AP/95/B/R

Storage Conditions: Store in air-tight, light resistant containers

Compiled By
(Analyst-QC)

03/03/2022



Approved By
(HOD-QC)

03/03/2022