



ALKALOIDS PRIVATE LIMITED (Unit-D)

Manufacturing Site: 25/3, Gundlapochampally, Medchal-Malkajgiri District, Telangana - 500100, INDIA
Ph No: +91-40-23792010

CERTIFICATE OF ANALYSIS

Product Name	: Hyoscine Butylbromide	Reference	: Ph.Eur
	: (CAS No :149-64-4)		
Batch No.	: 2521122	Quantity	: 1.500 Kg
A.R.No.	: QC/FG/057/22	Date of Analysis	: 06/12/2022
Date of Manufacturing	: Nov-2022	Date of Expiry	: Oct-2027

S.NO.	PARAMETERS	SPECIFICATIONS	RESULT
1.	Appearance	A white or almost white crystalline powder	Complies
2.	Solubility	Freely soluble in water and methylene chloride; sparingly soluble in anhydrous ethanol	Complies
3.	Identification		
	A) By specific optical rotation (5% w/v solution in water)	A) Should be -18.00° to -20.00°	-19.35°
	B) By Melting Point	B) Should be 139.0°C - 141.0°C	140.2°C
	C) By IR method	C) The I.R Spectrum of the sample must be concordant with that of Reference Standard / Working Standard	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.	Atidity or alkalinity	NMT 0.5mL of 0.01M Hydrochloric acid is required to change the color of indicator to reddish-violet	0.30 mL
6.	Specific Optical Rotation	Should be -18.00° to -20.00°	-19.35°
7.	Loss on Drying	NMT 2.50 % w/w	0.31%
8.	Sulphated Ash	NMT 0.10 % w/w	0.02%
9.	Assay (By Silver Nitrate Titration)	NLT 98.00 % & NMT101.00% Calculated on dry basis	99.77%
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-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
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S.NO.	PARAMETERS	SPECIFICATIONS	RESULT
Additional Tests (In-House Specifications)			
11.	Residual Solvents (by GC-HIS)	a) Methanol: NMT 500 ppm	30 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	6 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
13.	Bacterial Endotoxin (Gel Clot Method)	iv) Staphylococcus aureus: Should be Absent	Absent
		v) Enterobacteria: Should be Absent	Absent
		NMT 0.25 EU/mg	< 0.25 EU/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)

27/01/2023

Approved By
(HOD-QC)

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2248-7674

ALKALOIDS CORPORATION
8 BENTINCK STREET, KOLKATA - 700001, INDIA
GSTIN : 19AAEFA8293P1ZN PAN : AAEFA8293P

EXPORT INVOICE CUM PACKING LIST												Original for Receipt					
												Duplicate for Supplier/Transporter					
												Triplicate for Supplier					
Supply Meant for Export Under Letter of Undertaking without Payment of Integrated Tax (IGST)																	
ARN : AD1903220094559																	
Reverse Charges : No						Transportation Mode : AIR											
Invoice No. : DP-324/2022-23						Vehicle Number :											
Invoice Date : 02/02/2023						Purchase Order No. : # PO05167 Dated 09.01.2023											
State : WEST BENGAL						State Code : 19		Place of Supply : BRUSSELS / BELGIUM									
Details of Receiver I Billed to :							Details of Consignee I Shipped to :										
Name : TO ORDER							Name : TO ORDER										
Address : 2960 SINT-LENAARTS,							Address : 2960 SINT-LENAARTS,										
Country : BELGIUM							Country : BELGIUM										
Sr. No.	Name of Product / Service	HSN ACS	UOM	Qty	Rate	Amount	Less: Discount	Taxable Value	CGST Rate	CGST Amount	SGST Rate	SGST Amount	IGST Rate	IGST Amount	Total		
1	HYOSCINE BUTYL BROMIDE PH.EUR	29	KG	1.50	USD 2200.00	USD 3,300.00	-	USD 3,300.00	0.00%	-	0.00%	-	0.00%	-	USD 3,300.00		
		39	KGS														
		19	NET		PER KG												
		00		2.265 KGS. GROSS													
(BULK DRUG) (MANUFACTURED DRUG IN POWDER FORM)																	
(PACKED IN 1 HDPE DRUM CONTAINING 1.500 KGS. NET OF THE MATERIAL)																	
BATCH NO : 2521122 - 1.500 KGS.																	
MFG DT: 11/2022 EXP DT: 10/2027																	
FOB VALUE : RS. 2,61,727.00																	
MARKS: FSA CHEMICALS PO: #PO05167 HYOSCINE BUTYL BROMIDE BELGIUM NO. 1																	
BUYER : FAC SECUNDUM ARTEM NV (FSA CHEMICALS), BELGIUM																	
CORRESPONDING EXPORT UNDER ADVANCE AUTHORIZATION NO. 0211002191 Dated 29/03/2022 OF ALKALOIDS PRIVATE LIMITED																	
THIS IS A THIRD PARTY EXPORT. RODTEPY BENEFIT WILL ACCRUE TO ALKALOIDS CORPORATION. THIS EXPORT IS TOWARDS DISCHARGE OF OBLIGATION BY ALKALOIDS PRIVATE LIMITED UNDER THEIR ADVANCE AUTHORIZATION NO. 0211002191 Dated 29/03/2022																	
REGN. NO. WITH PHARMEXCIL PXL/ME/VII/4205 Valid upto 31-03-2024 OF ALKALOIDS CORPORATION &																	
REGN. NO. WITH PHARMEXCIL PXL/SSM/II/4323 Valid upto 31-03-2024 OF ALKALOIDS PRIVATE LIMITED																	
		1.50			USD			USD							USD		
		KGS			3,300.00			3,300.00							3,300.00		
Total Invoice Amount in Words : (Total US Dollar : Three Thousand Three Hundred only)									Total amount Before Tax			USD 3,300.00					
									Add : CGST			-					
									Add : SGST			-					
									Add : IGST			-					
									Tax Amount : GST			-					
									Total Amount After Tax			USD 3,300.00					
									GST Payable on Reverse Charges			N.A.					
Bank Details Bankers : CITIBANK N.A., 41 Chowringhee Road, Kolkata-700071, India IFSC : CITI00000001 Account No.: 0304296003 Beneficiary : ALKALOIDS CORPORATION., 8 Bentinck Street, Kolkata-700001, India GSTIN OF REGD. SUPPLIER 36AACCA6342E1Z0 - TAX INV. NO. U1/22-23/248 DT. 28/01/2023 - IGST AMT. RS. 205.80 : Terms and Conditions : PAYMENT TERMS : ADVANCE PAYMENT TERMS OF DELIVERY : CIP BRUSSELS AIRPORT/BELGIUM									(Common Seal)			Certified that the particulars given above are true and correct. For Alkaloids Corporation  Partner					