



Format No.: QA/38/F-01/01

ALKALOIDS PRIVATE LIMITED (Unit-I)

Manufacturing Site: 25/3, Gundlapochampally, R.R District, Telangana, INDIA
Ph No: +91-40-23792010

CERTIFICATE OF ANALYSIS

Product : **Hyoscine Hydrobromide** Reference : BP/Ph.Eur
Batch No. : 2610614 Quantity : 5.100 Kg
A.R No. : QC/FG/055/14 Date of Analysis: 28/06/14 & 01/07/14
Date of Manufacturing: June, 2014 Date of Expiry : May, 2019

S.No.	PARAMETERS	SPECIFICATIONS	RESULT
01	Appearance	White or almost white, crystalline powder or colorless crystals, efflorescent	Complies
02	Solubility	Freely soluble in water, soluble in ethanol (96 %)	Complies
03	Identification		
	A) By Specific Optical Rotation :-	It should be -24.00° to -27.00°	-25.82°
	B) By IR :-	Sample spectrum should be concordant with Reference / Working Standard	Complies
	C) By derivation:-	The Picrate derivative should melt between 188.0° C and 193.0°C	191.5°C to 191.7°C
	D) By color Test: -	To comply as per Ph.Eur.	Complies
	E) By Test of Bromide :-	Should be positive	Complies
04	Specific Optical Rotation	As per Identification Test A	Complies
05	pH (5 % solution in water)	Between 4.00 to 5.50	4.88
06	Water	Between 10.00% – 13.00 % w/w	12.12%w/w
07	Sulphated Ash	Not more than 0.10 % w/w	0.03% w/w
08	Assay	Not less than 99.00 % and not more than 101.00 %, calculated on anhydrous basis	99.68% w/w

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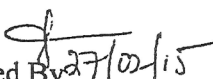
S.No.	PARAMETERS	SPECIFICATIONS	RESULT
09	Related substances (By HPLC)	Impurity A : NMT 0.10%	Not Detected
		Impurity B : NMT 0.50%	Below Disregard Limit
		Impurity C : NMT 0.10%	Not Detected
		Impurity D : NMT 0.10%	Not Detected
		Any other Impurity : NMT 0.10%	Not Detected
		Total Impurities : NMT 0.70 %	0.01%
Additional Test (In-House)			
10	Residual Solvents	Methanol : NMT 300 ppm	12ppm
		Acetone : NMT 500 ppm	Not Detected
		Methylene Chloride: NMT 60 ppm	Not Detected
11	Microbial limits		
	a) Total Microbial Count	NMT : 100 cfu/g	10cfu/g
	b) Yeast & Mould Count	NMT : 50 cfu/g	< 10cfu/g
	c) Pathogens		
	i) Escherichia coli	Should be Absent	Absent
	ii) Salmonellae	Should be Absent	Absent
	iii) Pseudomonas auruginosa	Should be Absent	Absent
	iv) Staphylococcus aureus	Should be Absent	Absent
v) Entrobacteria	Should be Absent	Absent	

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

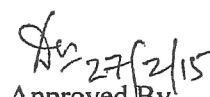
Drug License No.: 141/RR/AP/95/B/R

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

PC.No. 21054

Compiled By 
 (Analyst-QC)




 Approved By
 (HOD-QC)

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