



## ALKALOIDS PRIVATE LIMITED (Unit-I)

Manufacturing Site: 25/3, Gundlapochampally, Ranga Reddy District, Telangana-500100, INDIA

Ph No: +91-40-23792010

### CERTIFICATE OF ANALYSIS

|                          |                            |                  |              |
|--------------------------|----------------------------|------------------|--------------|
| Product Name             | : Hyoscine<br>Hydrobromide | Reference        | : BP/ Ph.Eur |
| Batch No.                | : 2680418                  | Quantity         | : 5.050 Kg   |
| A.R.No.                  | : QC/FG/027/18             | Date of Analysis | : 26/04/18   |
| Date of<br>Manufacturing | : April-2018               | Date of Expiry   | : March-2023 |

| S. No. | PARAMETERS                      | SPECIFICATIONS                                                                  | RESULT                |
|--------|---------------------------------|---------------------------------------------------------------------------------|-----------------------|
| 1.     | Appearance                      | White or almost white, crystalline powder or colorless crystals, efflorescent   | Complies              |
| 2.     | Solubility                      | Freely soluble in water, soluble in ethanol (96 %)                              | Complies              |
| 3.     | Identification                  | It should be -24.00° to -27.00°                                                 | -25.94°               |
|        | A) By Specific Optical Rotation |                                                                                 |                       |
|        | 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                 | 191.2°C               |
|        | D) By color Test                | To comply as per Ph.Eur.                                                        | Complies              |
|        | E) By Test of Bromide           | Should be positive                                                              | Complies              |
| 4.     | Specific Optical Rotation       | As per Identification Test A                                                    | -25.94°               |
| 5.     | pH (5 % solution in water)      | Between 4.00 to 5.50                                                            | 4.47                  |
| 6.     | Water                           | Between 10.00% – 13.00 % w/w                                                    | 12.17%                |
| 7.     | Sulphated Ash                   | Not more than 0.10 % w/w                                                        | 0.04%                 |
| 8.     | Assay                           | Not less than 99.00 % and not more than 101.00 %, calculated on anhydrous basis | 99.98%                |
| 9.     | Related substances<br>(By HPLC) | Impurity A: NMT 0.10%                                                           | Below Disregard Limit |
|        |                                 | Impurity B: NMT 0.50%                                                           | Below Disregard Limit |
|        |                                 | Impurity C: NMT 0.10%                                                           | Below Detection Limit |
|        |                                 | Impurity D: NMT 0.10%                                                           | Below Detection Limit |
|        |                                 | Any other Impurity: NMT 0.10%                                                   | Below Detection Limit |
|        |                                 | Total Impurities: NMT 0.70 %                                                    | Below Disregard Limit |



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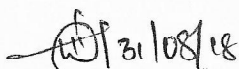
Product Name : **Hyosine** Reference : BP/ Ph.Eur  
                  : **Hydrobromide**  
Batch No. : 2680418 Quantity : 5.050 Kg  
A.R.No. : QC/FG/027/18 Date of Analysis : 26/04/18  
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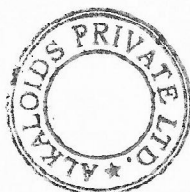
| S. No. | PARAMETERS                         | SPECIFICATIONS                 | RESULT                |
|--------|------------------------------------|--------------------------------|-----------------------|
| 10.    | <b>Additional Tests (In-House)</b> |                                |                       |
|        | <b>Residual Solvents</b>           | Methanol: NMT 300 ppm          | Below Detection Limit |
|        |                                    | Acetone: NMT 500 ppm           | Below Detection Limit |
|        |                                    | Methylene Chloride: NMT 60 ppm | Below Detection Limit |
| 11.    | <b>Microbial limits</b>            |                                |                       |
|        | a) Total Microbial Count           | NMT : 100 cfu/g                | < 10 cfu/g            |
|        | b) Yeast & Mould Count             | NMT : 50 cfu/g                 | < 10 cfu/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                |

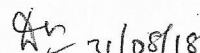
**REMARKS:-** The product conforms / does not conform to BP/Ph.Eur specifications.

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

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

  
Compiled By  
(Analyst-QC)



  
Approved By  
(HOD-QC)