



ISO 9001:2015 CERTIFIED      CERTIFICATE OF ANALYSIS

|                       |                                                                                                                                                                            |  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Product Name          | Methyl-6β-Naltrexol TFA                                                                                                                                                    |  |
| Molecular Formula     | C <sub>21</sub> H <sub>28</sub> NO <sub>4</sub> + (Free Base); C <sub>23</sub> H <sub>28</sub> F <sub>3</sub> NO <sub>6</sub> (TFA Salt)                                   |  |
| Molecular Weight      | 358.46 (Free Base); 471.47 (TFA Salt)                                                                                                                                      |  |
| Batch Number          | XX-XXXX                                                                                                                                                                    |  |
| Batch Quantity        | XXX                                                                                                                                                                        |  |
| Date of Manufacturing | DD-MM-YYYY                                                                                                                                                                 |  |
| Date of Analysis      | DD-MM-YYYY                                                                                                                                                                 |  |
| Next Retest Date      | DD-MM-YYYY                                                                                                                                                                 |  |
| Catalogue Number      | XX                                                                                                                                                                         |  |
| CAS Number            | NA                                                                                                                                                                         |  |
| COA Number            | PA-XXXX                                                                                                                                                                    |  |
| IUPAC Name            | (4R,4aS,7R,7aR,12bS)-3-(cyclopropylmethyl)-4a,7,9-trihydroxy-3-methyl-2,3,4,4a,5,6,7, 7a-octahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinolin-3-ium 2,2,2-trifluoroacetate |  |
| Storage and Handling  | 2-8°C                                                                                                                                                                      |  |

| Sl. No | * Test                                        | Result |
|--------|-----------------------------------------------|--------|
|        | Description                                   |        |
| 1.     | Identification i) By IR ii) By NMR iii) By MS | --     |
| 2.     | Chromatographic Purity (% by HPLC)            | --     |

Remarks: \*Test or tests as mentioned above may vary as per the product nature or customer's requirement

| Function      | Compiled by         | Reviewed by         | Reviewed by       | Approved by       |
|---------------|---------------------|---------------------|-------------------|-------------------|
| Name          | xxx                 | xxx                 | xxx               | xxx               |
| Department    | Pharma Standards QC | Pharma Standards QC | Quality Assurance | Quality Assurance |
| Sign and Date |                     |                     |                   |                   |

|                  |                                         |
|------------------|-----------------------------------------|
| Attachments      | IR, NMR, MS spectra, HPLC Chromatogram. |
| Date of Shipment | DD-MMM-YYYY                             |

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