

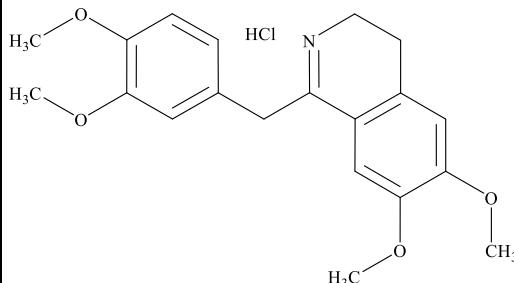
# Certificate of Analysis

Certificate No.: 20200715027

Date: July 15, 2020

Retest date: July 9, 2023

|  |  |
|--|--|
| <b>Compound Name:</b> Papaverine EP Impurity C HCl (3,4-Dihydropapaverine HCl) |  |
| <b>Synonyms:</b>   | 1-(3,4-dimethoxybenzyl)-6,7-dimethoxy-3,4-dihydroisoquinoline, hydrochloride (1:1) |
| <b>TLC Catalogue Number:</b>   | P-483  |
| <b>CAS Number:</b>   | 5884-22-0  |
| <b>Molecular Weight:</b>   | 341.41 36.46   |
| <b>Molecular Formula:</b>  | C <sub>20</sub> H <sub>23</sub> NO <sub>4</sub> . HCl                              |
| <b>Source:</b>   | TLC Pharmaceutical Standards   |
| <b>Source Lot No.:</b>   | 2923-067A2   |
| <b>Storage Conditions:</b>   | Store at 2-8 °C  |
| <b>Solubility:</b>   | Methanol, DMSO, Water  |



| Test Description               | Specifications                 | Results         |
|--------------------------------|--------------------------------|-----------------|
| <b>Visual Description</b>      | Yellow solid                   | <b>Conforms</b> |
| <b>Identification</b>          |                                |                 |
| IR                             | Conforms to structure          | <b>Conforms</b> |
| MS                             | Conforms to structure          | <b>Conforms</b> |
| <sup>1</sup> H NMR             | Conforms to structure          | <b>Conforms</b> |
| <b>Purity (HPLC)</b>           | Not less than 95.0%            | <b>99.4%</b>    |
| <b>Impurity (HPLC)</b>         | RT 5.10, 0.16%; RT 5.83, 0.12% |                 |
| <b>Water Content (KF)</b>      | N/A                            | <b>3.7%</b>     |
| <b>Residual Solvents (NMR)</b> | No residual solvent            |                 |
| <b>Assay (%)</b>               | Not less than 90.0%            | <b>95.7%</b>    |
| <b>Recommendation:</b>         | <b>Released.</b>               |                 |

| Name                      | Department          | Signature | Date |
|---------------------------|---------------------|-----------|------|
| Reviewed and approved by: | Analytical Services |           |      |
| Approved by:              | Quality Assurance   |           |      |

**Attachments:** HPLC, IR, MS and NMR spectra.