

# Certificate of Analysis

## Reference Material & Standard

|                    |                                                 |                   |                                           |
|--------------------|-------------------------------------------------|-------------------|-------------------------------------------|
| Product Name:      | Buprenorphine EP Impurity I                     | Catalogue Number: | CS422417                                  |
| Synonyms:          | N/A                                             | Lot Number:       | 0222-SA-7657                              |
| CAS Number:        | 89663-73-0                                      | Expiry Date:      | Feb 21, 29                                |
| Molecular Formula: | C <sub>28</sub> H <sub>37</sub> NO <sub>3</sub> | Storage:          | -20°C±5°C Protected from light and Sealed |
| Molecular Weight:  | _x000D_ _x000D_ _x000D_ 435.6 _x000D_           |                   |                                           |

Warning:



Chemical Structure: N/A

| Test Items      | Method            | Results                  |
|-----------------|-------------------|--------------------------|
| Appearance      | Visual inspection | White to Off-White Solid |
| Identification: | LC&HNMR           | Confirmed                |
| Purity:         | HPLC              | 97.484%                  |
| Uncertainty     |                   | ±2.0%                    |

## Comment:

The uncertainty values are the expanded uncertainty and represent an estimated standard deviation equal to the positive square root of the total variation of the uncertainty of components. A normal distribution is assumed and a coverage factor of K=2 is chosen using approximately a 95% confidence level.

Signature:

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Date: Feb 22, 25

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## Directions:

1. *Intended use: This product is suitable for identification and quantification of the analyte(s), instrument calibration, method development and quality control in analytical and R&D applications. It is not intended for administration to humans or animals, and shall not be used to diagnose, treat or cure any diseases.*
2. *Minimum sample size: 1mg is recommended as the minimum sample size.*
3. *Metrological traceability: This product meets the requirements of ISO 17034 and is traceable to NMI through an unbroken chain of comparisons.*
4. *Instructions for handling and correct use: Handling in a well-ventilated place.*

## Document Version:

| Revision No. | Date       | Reason for Revision |
|--------------|------------|---------------------|
| 01           | Feb 22, 25 | First release.      |

