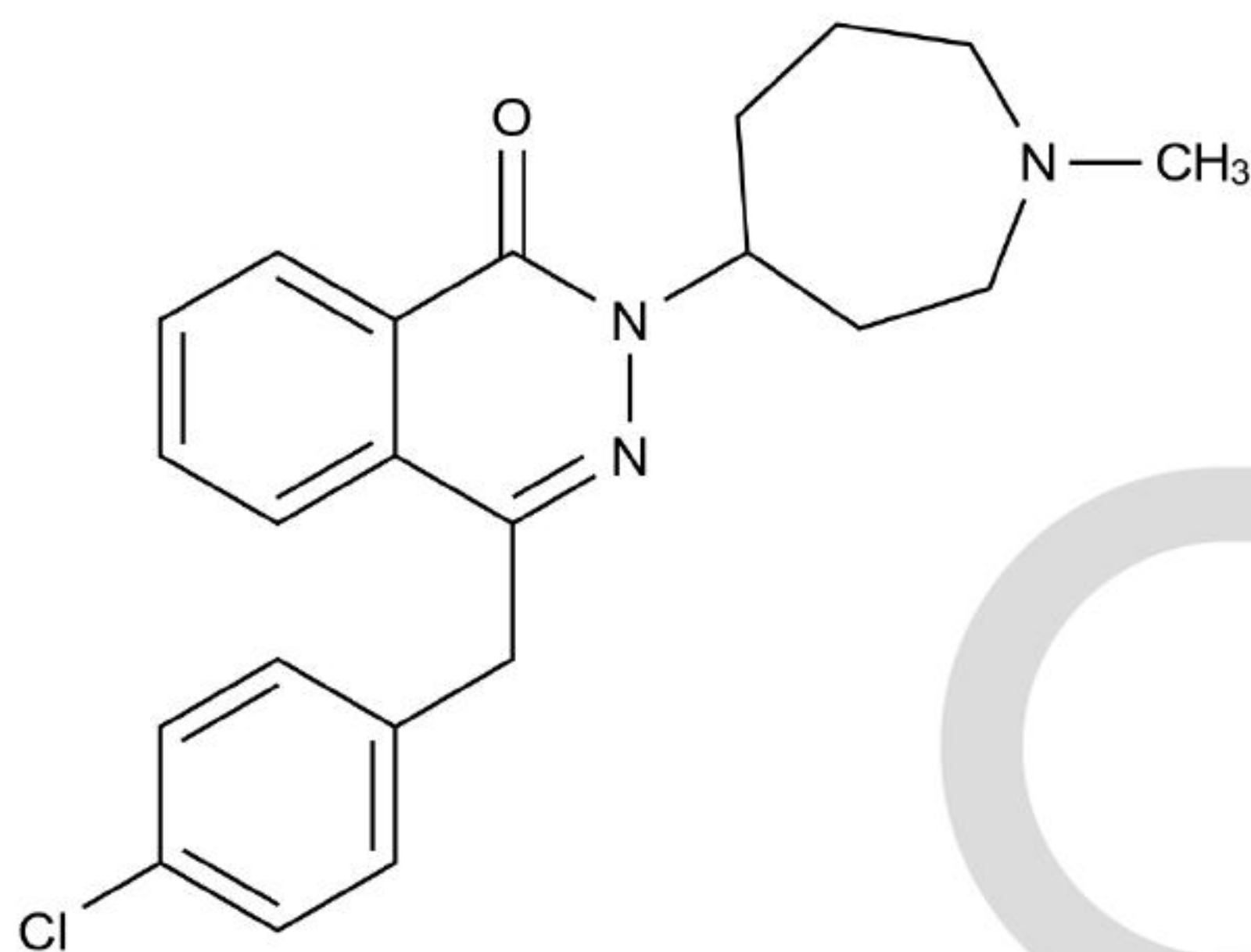


# Certificate of Analysis

## Reference Material & Standard

|                    |                                                    |                   |                                                                                     |
|--------------------|----------------------------------------------------|-------------------|-------------------------------------------------------------------------------------|
| Product Name:      | Azelastine                                         | Catalogue Number: | CCAD303732                                                                          |
| Synonyms:          | N/A                                                | Lot Number:       | 1016-RE-0117                                                                        |
| CAS Number:        | 58581-89-8                                         | Expiry Date:      | Oct 19, 2027                                                                        |
| Molecular Formula: | C <sub>22</sub> H <sub>24</sub> ClN <sub>3</sub> O | Storage:          | -20°C±5°C Protected from light and Sealed                                           |
| Molecular Weight:  | 381.90                                             | Warning:          |  |

### Chemical Structure:



| Test Items     | Method            | Results     |
|----------------|-------------------|-------------|
| Appearance     | Visual inspection | White Solid |
| Identification | LCMS&HNMR         | Confirmed   |
| Purity         | HPLC              | 99.848%     |
| Loss On Drying | TGA               | 2.3072%     |
| Assay          |                   | 97.5%       |
| Uncertainty    |                   | ±2.0%       |

## Comment:

1. The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Loss On Drying) \* Purity HPLC (%) / 100%

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

2. 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:

Prepared by:

*Nice*

Reviewed by:

*Lisa*

Aproved by General Manager:

*David*

Date: Oct 20, 2023

Date: Oct 20, 2023

Date: Oct 20, 2023

