



Quick guide to our phyproof® Reference Substances Certificate of Analysis

Certificate of analysis

Report-No.: 104935443 - 99 002
 Batch: 15605
 Article: 80003 Tomatidine (supplied as HCl salt)
 Quantity: 3 x 500 mg

| Test | Unit | Limit | Testresult |
|--|------|-------------------|------------|
| Appearance, SOP 100005 | | powder | Conform |
| Color, SOP 100006 | | white | Conform |
| Solubility, SOP 105001: DMSO | | sparingly soluble | Conform |
| Identification (HPLC-HR/MS), SOP 204125 | } | Conform | Conform |
| Identification (IR-spectroscopy, Ph.Eur. 9.0, 2.2.24)/USP 42 NF 37 <197>), SOP 206000 | | Conform | Conform |
| Identification (1H-NMR-spectroscopy), (outsourced), SOP 206010 | | Conform | Conform |
| Identification (13C-NMR-spectroscopy), (outsourced), SOP 206020 | | Conform | Conform |
| Water content, (micro determination, coulometric titration), Ph.Eur. 10.0., 2.5.32, SOP 304291: Mean value | % | | < 0.3 |
| Chloride (argentometric titration), No. 400897 (double analysis, outsourced): Mean value | % | | 7.65 |
| Tomatidine (HPLC), method 1 (% AU), SOP 401219 | % | >= 95.00 | 98.84 |
| Residual solvents, (headspace-GC), SOP 805765: Residual solvents | % | | < 0.05 |
| Inorganic impurities, (ICP-MS), for reference substances, SOP 811701: | | | |
| Sodium | % | | < 0.1 |
| Potassium | % | | < 0.1 |
| Magnesium | % | | < 0.1 |
| Calcium | % | | < 0.1 |
| Aluminium | % | | < 0.1 |
| Phosphorus | % | | < 0.1 |
| Sulfur | % | | < 1.0 |
| Content* (regarding the counterion as an inorganic impurity. For detailed information please see the attached data sheet!), SOP 890002 | % | | 91 |

Assessment:
 The above mentioned reference substance meets the specification.

- 5 *The absolute content is calculated considering the chromatographic purity, and if available, the content of water, residual solvents and inorganic impurities according to the following formula:
 $Content = (100\% - water\ content\ (\%) - residual\ solvents\ (\%) - inorganic\ impurities\ (\%)) \times chromatographic\ purity\ (\%) / 100.$
- 6 The chromatographic purity is checked regularly: the last analysis has been performed in April 2020.
- 6 The reference substance cannot be documented with an expiry date. The pack is closed and is recommended to be stored as indicated. The unopened product is guaranteed to fulfill the specifications of this analytical report for a period of 60 months. Once opened we can no longer guarantee the stability of the material.

Vestenbergsreuth, 16.04.20



Prices, MSDS, exemplary CoA for download, FAQ and much more is available on our website. Order phyproof® Reference Substances with just a few clicks. Please visit:

<https://phyproof.phytoLab.com/en/>

1

Report number:

Every certificate has a unique report number. This number can also be found on our labels, so the corresponding certificate can easily be identified. This guarantees complete traceability.

Batch number:

Please note: Our worldwide distribution partner Sigma-Aldrich / Millipore-Sigma uses 8-digit batch numbers. You can download our CoA from their website (www.sigmaaldrich.com). Just visit the respective product page and enter the batch number under „Certificate of Analysis“ or „Documents“.

Quantity:

We give the exact initial weight to two decimal places on the inner label of the vial to enable the production of stock solutions. Only the nominal order quantity is indicated on the outer label and the certificate of analysis.

2

Supplementary data / Spectra:

Spectra (e.g. for IR, NMR, UV, MS) for all identification tests as stated on the CoA are provided upon request and with your order.

3

LOQ:

A value below the limit of quantification (LOQ) is indicated with a less than symbol (<). The result is considered to be zero with regard to the calculation of the absolute content (compare formula below).

4

Absolute content:

The absolute content is given on the certificate when the reference substance is certified as a primary reference substance. If the reference substance is provided as a salt the counter ion is treated as an impurity and deducted from the absolute content (compare formula below).

5

Calculation of absolute content:

The absolute content in this example is calculated as follows:
 $(100\% - 0\% (water) - 0\% (residual\ solvents) - 7.65\% (inorganic\ impurities)) \times 98.84\% (chromatographic\ purity) / 100 = 91\%$
 (absolute content is rounded and given with no decimal places).

6

Manufacturing date / Expiry date:

The date of the last analysis equals the manufacturing date. The given stability period starts from the month the CoA was issued. In this case this corresponds to an expiry date of April 2025.

