CERTIFICATE OF ANALYSIS

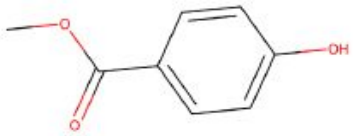
aAurum

**Propylparaben**

1

Propyl 4-hydroxybenzoate

| | |
|---|---|
| Product Number: | 10002-1G |
| Lot Number: | AA0004 |
| Appearance: | White powder |
| Expiration: | 31-May-30 |
| Storage: | Room Temperature (2 to 30 °C) |
| Shipping: | Ambient |
| Chemical Formula: | $C_{10}H_{12}O_3$ |
| Molecular weight: | 180.2 |
| CAS No.: | 94-13-3 |
| Date of Manufacture: | 6-May-26 |
| Bulk Material Lot: | AA0003 |
| Country of Origin: | Japan |




**Certified Properties**

2

| Certified Value (Purity) | Uncertainty | Units | Coverage Factor (k) | Basis, Reported As | Method |
|---|---|---|---|---|---|
| 100.0 | ±0.2 | % | k=2.00 | As Is, $C_{10}H_{12}O_3$ | qNMR |

**Metrological Traceability:**

3

This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10 % relative error. Fill volume to predetermined specifications is gravimetrically verified throughout the dispensing process using qualified and calibrated balances. Further traceability to a corresponding Primary Standard may be achieved through direct comparison assay. Where a Primary Standard is available, the assay value will be included in the specified section of the CofA.

**Intended Use:** Intended for R&D and analytical use only. Not for drug, household or other uses.



1

**Full Material Traceability**

Each unit is uniquely identified and linked to its originating bulk material and manufacturing record, ensuring complete traceability from production through final release.

2

**Certified Value with Measurement Uncertainty**

The assigned value is established using validated methods and reported with expanded uncertainty (k=2), providing approximately 95% confidence in accordance with ISO GUM principles.

3

**Metrological Traceability to SI Units**

Measurements are traceable through calibrated instrumentation and NIST-traceable standards, ensuring accuracy, comparability, and compliance with ISO/IEC 17025 requirements.

**Minimum sample size:** 15 mg

**Instructions for handling:** Do not dry, use on the as is basis. The internal pressure of the container may be slightly different from the atmospheric pressure at the user's location. Open slowly and carefully to avoid dispersion of material.

Analytical Results Summary

4

| Property | Result | Units | Specification | Method |
|---|---|---|---|---|
| Appearance | White Powder | | White Powder | Visual |
| Water Content | <0.02 | % | * | Karl Fisher (KF-C) |
| Chromatographic Impurities | None | % | * | HPLC |
| Melting Range | 96.5 to 97.9 | °C | 96 to 99 | Melting Range |
| Identity to USP (IR-Spectrum) | 0.9998 | $R^2$ | >0.95 | FTIR Spectrum |
| Identity to EP (IR-Spectrum) | 0.9997 | $R^2$ | >0.95 | FTIR Spectrum |
| Identity (Mass Spectrometry) | 181.0862 | *m/z* | 181.0859 (theoretical) | LC/MS Orbitrap |
| Identity (NMR) | Conform | | Conform | H NMR |

*Results support the certified value.

**Certification issue date:** 19 May 2026

Jenna Milliken, Technical Approver

Michelle Nunnaley, Quality Assurance

Aurum Standards Group, 1460 Commerce Drive, Laramie, WY 82070
Tel. 1 307 460-2261; www.aurumstandardsgroup.com



4

**Validated Characterization Approach**
Certified values are established using scientifically recognized methods (e.g., qNMR) with traceable reference standards and controlled experimental conditions.

aAurum

## Purity and Uncertainty Assessment

Certification Process Details:

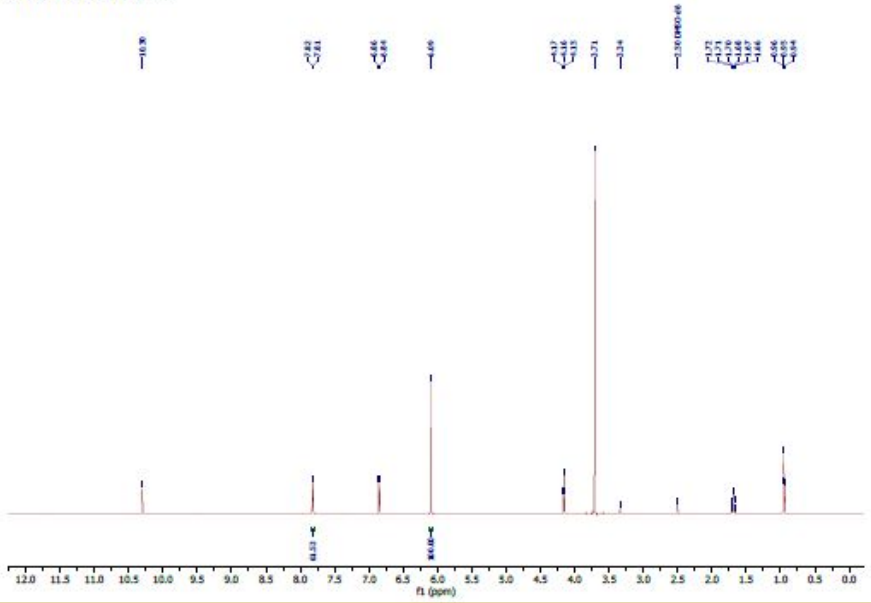
5

$$P_{Sample} = \frac{I_{Analyte}}{I_{CRM}} \cdot \frac{N_{CRM}}{N_{Analyte}} \cdot \frac{M_{Analyte}}{M_{CRM}} \cdot \frac{m_{CRM}}{m_{Sample}} \cdot P_{CRM}$$

| | | | |
|---|---|---|---|
| $P_{Sample}$ | Purity of samples as mass fraction (%) | $N_{CRM}$ | Number of CRM nuclei |
| $P_{CRM}$ | Purity of CRM as mass fraction (%) | $M_{Analyte}$ | Molecular mass of the analyte (g/mol) |
| $I_{Analyte}$ | Integral of the analyte signal | $M_{CRM}$ | Molecular mass of the CRM (g/mol) |
| $I_{CRM}$ | Integral of the CRM signal | $m_{Sample}$ | Mass of sample (mg) |
| $N_{Analyte}$ | Number of analyte nuclei | $m_{CRM}$ | Mass of CRM (mg) |

**qNMR**

Method Name: M00004
Condition: Bruker Avance III 600 MHz NMR
Solvent: DMSO-d6
Internal Standard (CRM): 1,3,5-Trimethoxybenzene, 74599; Lot: BCCL3544
Mass Fraction, n = 9




**Associated uncertainty:** The expanded uncertainty (U) is reported as a quantitative value in the same units as the certified value and is calculated in accordance with the principles of the ISO Guide to the Expression of Uncertainty in Measurement (GUM). In general, the expanded uncertainty is obtained by multiplying the combined standard uncertainty by a coverage factor k = 2, providing a level of confidence of approximately 95%.



5

**Primary Value Assignment via qNMR**

The certified purity value is established using quantitative NMR (qNMR), a primary ratio method that enables direct measurement of analyte content relative to a traceable reference standard. This approach minimizes method-dependent bias and provides a metrologically sound basis for value assignment in accordance with ISO 17034 principles.

The uncertainty includes contributions from characterization, between-bottle homogeneity, and long-term stability, as applicable. The reported uncertainty is not intended to be used as a tolerance limit for compliance assessment but reflects the dispersion of values that could reasonably be attributed to the measurand.

$$U_{crm} = \left(\sqrt{u^2_{characterization} + u^2_{homogeneity} + u^2_{stability}}\right) \times k$$

**Homogeneity Assessment:**

6

Homogeneity was assessed in accordance with ISO 33405:2024, in support of ISO/IEC 17034 requirements, using a random stratified sampling design. Selected units were analyzed under repeatability conditions and evaluated by analysis of variance (ANOVA).

**Analytical Method:** qNMR

**Sample Size:** 15 mg

No statistically significant between-unit variability was observed at the chosen confidence level. The material is considered sufficiently homogeneous for the intended use, and any contribution from heterogeneity is included in the stated uncertainty.

**Stability Assessment:**

Stability was assessed in accordance with ISO 33405:2024, in support of ISO/IEC 17034, using a representative grouping approach for structurally similar materials (Section 8.2.3). Units were analyzed at defined intervals and evaluated for trends using appropriate statistical methods.

No statistically significant change in the assigned value(s) was observed. The material is considered stable for the stated period under recommended storage conditions, and any contribution from instability is negligible or included in the stated uncertainty if applicable.

**Traceability Assay:**

7

Comparative assay demonstrates direct traceability to Pharmacopeial Standards.

Assay vs. USP Reference Standard (1577008)

| Assay Value | Basis, Reported As | USP Lot | Labeled Content | Method Traceability |
|---|---|---|---|---|
| 0.9989 mg/mg | As Is, C10H12O3 | R14640 | 1.00 mg/mg | USP GUID-A5F6FE5D-7F2E-4A80-B93F-485DACE8250A_2 |

Assay vs. EP Reference Standard (P3650000)

| Assay Value | Basis, Reported As | EP Batch | Labeled Content | Method Traceability |
|---|---|---|---|---|
| 100.01 % | As Is, C10H12O3 | 4.0 | 99.6 % | EP 01/2022:0431 |



6

**Demonstrated Material Consistency**
Homogeneity and stability are statistically evaluated in accordance with ISO 33405 to confirm that material properties remain consistent across units and over time.

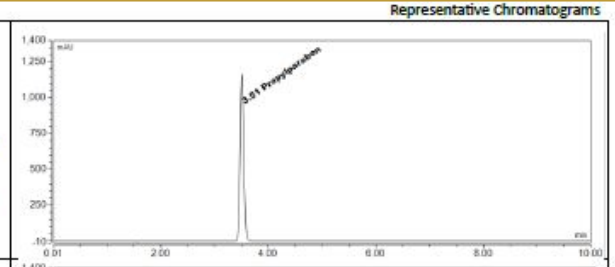
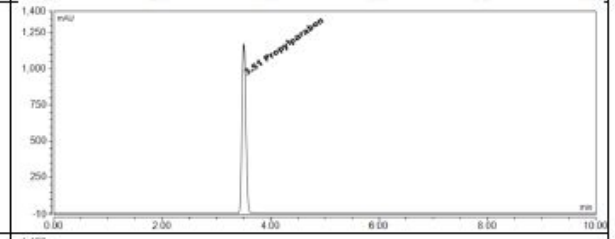
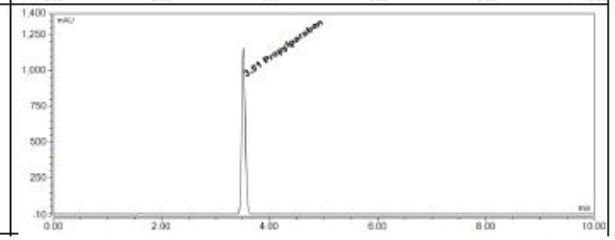
7

**Comprehensive Analytical Confirmation**
Orthogonal techniques confirm identity, purity, and absence of impurities, supporting the assigned certified value.

aAurum

8

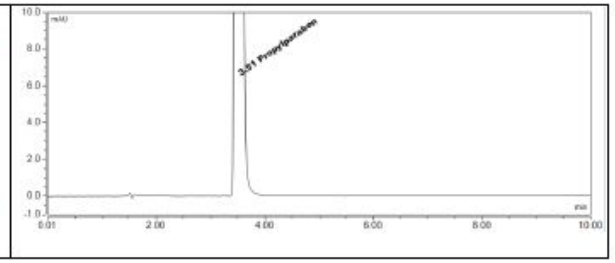
HPLC — Representative Chromatograms

| | |
|---|---|
| Method Name: M00001<br>Mobile Phase A: 6.8 g/L Potassium Phosphate Monobasic in Water<br>Mobile Phase B: Methanol<br>Mobile Phase Ratio: 35:65 (A:B)<br>Flow Rate: 0.8 mL/min<br>Column: Ascentis Express C18 150 mm x 4.6 mm x 5 µm<br>Column Temperature: 30 °C<br>Injection Volume: 10 µL<br>Detector: DAD, Wavelength: 272 nm<br><br>Aurum Lot: AA0003 |  |
| USP Lot: R14640 |  |
| EP Batch: 4.0 |  |

Impurity Assessment

9

HPLC

| | |
|---|---|
| Method Name: M00001<br>Mobile Phase A: 6.8 g/L Potassium Phosphate Monobasic in Water<br>Mobile Phase B: Methanol<br>Mobile Phase Ratio: 35:65 (A:B)<br>Flow Rate: 0.8 mL/min<br>Column: Ascentis Express C18 150 mm x 4.6 mm x 5µm<br>Column Temperature: 30 °C<br>Injection Volume: 10 µL<br>Detector: DAD, Wavelength: 272 nm<br><br>No impurities observed |  |



8

## Method Details

All methods used are clearly identified and the corresponding parameters are included. Representative chromatograms are provided for the Aurum lot alongside the appropriate pharmacopeia reference lots, enabling a direct, like-for-like comparison of retention time and peak profile.

9

## Impurity Analysis

A dedicated impurity assessment screens the material for related substances by chromatographic separation. The outcome is reported to confirm the orthogonal analyses being performed.

## Identity Assessment

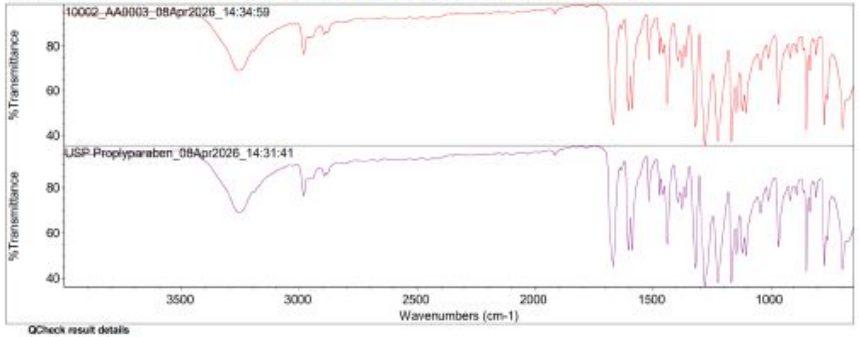
**FTIR**

Method Name: M00005

Instrument: Nicolet iS10

10

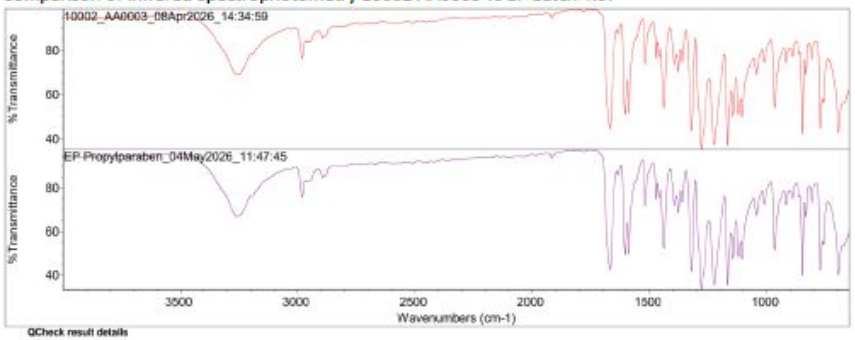
Comparison of Infrared Spectrophotometry 10002 AA0003 vs USP lot R14640:




QCheck result details

Correlation: 0.9998

Comparison of Infrared Spectrophotometry 10002 AA0003 vs EP batch 4.0:




QCheck result details

Correlation: 0.9997



10

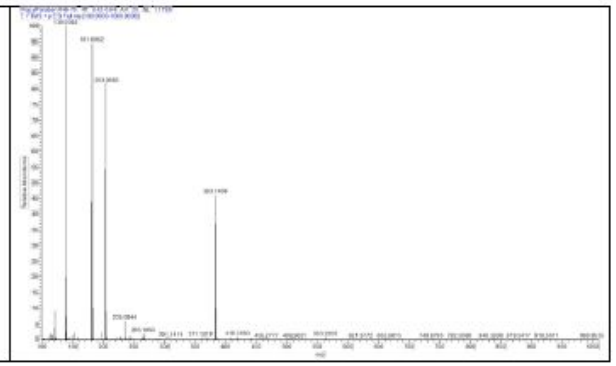
**Qualitative Identification**

Confirms the identity of the material and offers further traceability to the appropriate pharmacopeial standards. Infrared spectrophotometry (FTIR) compares the material's characteristic absorption fingerprint directly against both USP and EP reference standards. The strong spectral correlation across all diagnostic bands provides independent verification of chemical identity, while cross-referencing to compendial lots reinforces traceability and supports confident acceptance for regulated use.

Aurum

**Mass Spectrometry**

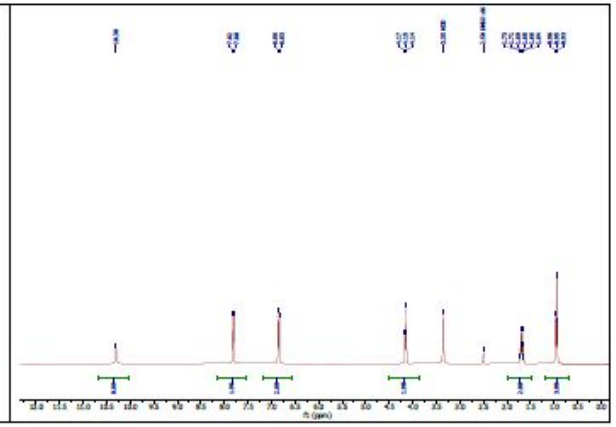
Method Name: M00002
Source:HESI
Polarity: Positive
Spray Voltage: 3500 V
Capillary Temperature: 250 °C
Detector: Thermo Scientific Q Exactive HF-X Hybrid Quadrupole-Orbitrap MS



11

**H NMR**

Method Name: M00003
Condition: Bruker Avance III 600 MHz NMR
Solvent: DMSO-d6



**Disclaimer:** The responsibility for assessing the suitability of this material for any specific use rests solely with the purchaser. Aurum Standards Group does not provide any express or implied warranties beyond confirmation that the product conforms to Aurum's established quality control criteria at the time of release. No representation is made regarding the fitness of this product for a specific purpose or application.

| Revision No. | Date | Reason for Revision |
|---|---|---|
| AA0004.01 | 19 May 2026 | Initial batch release |

12



11

**Mass and Structural Confirmation**
High-resolution ESI Orbitrap analysis confirms the molecular mass and elemental composition, supporting unambiguous identification of the material. The 600 MHz 1H spectrum in DMSO-d6 verifies the molecular structure and assesses purity through characteristic signal assignment and integration.

12

**Independent Review and Release**
Each CofA is reviewed and approved by qualified personnel to ensure compliance with Aurum's quality management system.