

## Quartz Plate Calibration Accredited by ISO/IEC 17025

### Introduction

Verifying accuracy is crucial for reliable measurements using analytical instruments. The accuracy inspection is often performed by checking the deviation of the measured value from the known value. For polarimeters, sucrose solutions are widely used for accuracy inspection. However, solution samples present challenges when used as reference materials. For example, concentration errors may occur during their preparation, or expiration dates need to be considered. As a result, quartz plates are becoming popular for accuracy inspection since they do not need special preparation and are very stable.

Pharmacopoeias specify methods for inspecting the accuracy of optical rotation measurements, including the use of a quartz plate as a reference material (Table 1). In the U.S. pharmacopoeia (USP), reference materials must have an expanded uncertainty associated with a calibration performed by a national metrology institute that is signatory to the International Committee for Weights and Measures Mutual Recognition Arrangement (CIPM MRA) or an ISO/IEC 17025 accredited calibration laboratory where the accreditation body is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA).<sup>1)</sup>

JASCO Corporation Calibration Division is accredited by ISO/IEC 17025 and provides a calibration value for quartz plates together with an expanded certainty, compliant with the accuracy inspection defined by USP-NF 2024, Issue 3. This report describes the quartz plate products and the calibration service that JASCO offers.



Fig. 1 P-4000 series polarimeter

Table 1 Accuracy test in pharmacopoeias

| Pharmacopoeia                             | Description   |
|---|---|
| U.S. Pharmacopoeia (USP-NF 2024, Issue 3) | “Verify the accuracy of the polarimeter at the operating wavelength(s) by measuring a certified optical rotation reference material having an associated expanded uncertainty. <u>Typically, quartz plate reference standards with certified optical rotation values are used.</u> Alternatively, other suitable certified reference materials or reference standards may be used.” <sup>1)</sup> |
| European Pharmacopoeia (EP11.0)           | “The accuracy of the scale is checked near the value to be measured or over an appropriate range, <u>usually by means of certified quartz plates.</u> Other certified reference materials may also be suitable (e.g sucrose solutions).” <sup>3)</sup>  |
| Japanese Pharmacopoeia (JP18)             | “Accuracy of the scale of the apparatus is verified by measuring the optical rotation of a solution of sucrose for optical rotation if the reading indicates the value of its known specific optical rotation. <u>For daily verification an optical rotation known quartz plate may be used for this purpose.</u> ” <sup>2)</sup>   |

### Keywords

Polarimeter, quartz plate, instrument management, instrument maintenance, validation, accuracy test, U.S. pharmacopoeia (USP), European pharmacopoeia (EP), Japanese pharmacopoeia (JP), ISO/IEC 17025, calibration, expanded uncertainty.

## Our Products and Service

### Quartz Plates

JASCO offers four types of quartz plate with different optical rotations of +2°, -2°, +17°, and -17°. Use of a quartz plate whose optical rotation is closest to that for the customer's sample is recommended. Some examples are given below.

Choosing -2° quartz plate for 50 mg/mL of ephedrine hydrochloride in water (1.0 dm)

Specific rotation  $[\alpha]_D^{25}$  : -33.0° to -35.5°<sup>1)</sup>

Optical rotation: -1.65° to -1.78° \*

Choosing +17° quartz plate for 260 mg/mL of sucrose (1.0 dm)

Specific rotation  $[\alpha]_D^{20}$  : +66.3° to +67.0°<sup>1)</sup>

Optical rotation: +17.24° to +17.42° \*

\*The optical rotation was calculated from the specific rotation.



Fig. 2 Quartz plate

### Calibration

JASCO Corporation Calibration Division offers a calibration service for the four types of quartz plate described above. A calibration certificate is provided with a calibration value and an expanded uncertainty obtained using the D-line emission from a sodium (Na) lamp.

Table 2 Calibration results shown in the certificate

| Item                             | Description  |
|----------------------------------|--|
| Optical rotation at 20 °C / °    | Calibration value for the corresponding quartz plate |
| Expanded uncertainty / °         | 0.003  |
| Wavelength / nm                  | 589.44<br>D-line from Na lamp (in vacuum)            |
| Light-source aperture / mm       | ø2   |
| Sample compartment aperture / mm | ø8   |

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| Calibration Certificate  |  |
|--|--|
| <p>Page 1 of 2 (E)<br/> <br/>           Certificate No. : LQPA-0103<br/>           Date of issue : 21 Oct. 2024</p>  |  |
| <p><b>Calibration Certificate</b></p>  |  |
| Customer Name  | : JASCO Corporation  |
| Customer Address   | : 2967-5, Inakawa-machi, Hachioji, Tokyo 192-8537, Japan   |
| Applicable Product   | : Jasco-P Practical standard quartz control plate 033  |
| Model Name   | : QCP-033  |
| Serial No.   | : A033141241   |
| Calibration Item   | : Optical rotation   |
| Calibration Method   | : As per W0695   |
| Date of Calibration  | : 21 Oct. 2024   |
| Place of Calibration   | : 2967-5, Inakawa-machi, Hachioji, Tokyo 192-8537, Japan<br>JASCO Corporation Calibration Division |
| <p><b>JASCO Corporation Calibration Division</b><br/>           2967-5, Inakawa-machi, Hachioji, Tokyo 192-8537, Japan<br/>           Approved by : Mamoru Amano<br/>           Signature : </p>   |  |
| <p><small>This certificate guarantees that the calibration results are in accordance with measurement standards traceable to recognized national standards.<br/>           This certificate may not be reproduced other than in full, except with the written approval of the issuing laboratory.<br/>           The laboratory is Japan Accreditation Board (JAB) accredited calibration laboratory that meets the requirements of ISO/IEC 17025.</small></p> |  |

  

| Calibration Results   |   |
|---|---|
| <p>Page 2 of 2 (E)<br/> <br/>           Certificate No. : LQPA-0103</p>   |   |
| <p><b>Calibration Results</b></p>   |   |
| <b>Results</b>  |   |
| Optical Rotation at 20 °C [°]   | : 0.340 *                                   |
| Expanded Uncertainty [°]  | : 0.003 *                                   |
| <b>Measurement Conditions</b>   |   |
| Wavelength [nm]   | : 589.44 nm, Sodium lamp D line (in vacuum) |
| Light-source aperture [mm]  | : ø 2                                       |
| Sample compartment aperture [mm]  | : ø 8                                       |
| <b>Note</b>   |   |
| <p>The expanded uncertainty is determined by a coverage factor of k=2, providing a confidence level of approximately 95%.</p>   |   |
| <b>Calibration Method</b>   |   |
| <p>The reference polarimeter, which was used for measurement of the quartz control plate, was calibrated using standard quartz control plates calibrated by PTB (Physikalisch-Technische Bundesanstalt), the National Metrology Institute of Germany.<br/>           The optical rotation range of these standard quartz control plates covers the optical rotation for the quartz control plate. The measured optical rotation for the quartz control plate was converted to the optical rotation at 20 °C using equation (1).<br/>           Temperature of all of the quartz control plates was measured using an internal thermometer that was calibrated traceable to international standards by the ILAC MRA accredited calibration laboratory.</p> |   |
| $w_{\text{c}} / \alpha_{\text{c}} = (589.44 \text{ nm}) \times 1.0 \times 0.000144 (t - 20) \quad (1) *$  |   |
| <p>α<sub>c</sub> (°) : measured optical rotation at 1 °C<br/>           α<sub>w</sub> (°) : optical rotation at 20 °C</p>   |   |
| <b>Reference</b>  |   |
| <p>(1) JCMMA Specification and Standard SP5-1 (2017) Polarimetry and the International Sugar Scale - Official</p>   |   |

Fig. 3 Example of calibration certificate

## Conclusions

The use of quartz plates enables efficient accuracy tests for polarimeters. In addition, using quartz plates calibrated by an ISO/IEC 17025 accredited laboratory ensures that the accuracy test meets the requirements specified by USP-NF 2024, Issue 3. The P-4000 series polarimeters have a validation function that provides instrument inspections compliant with USP, EP, and JP.

## Related Application Note

200-PL-0010 Validation Compliant to Pharmacopoeia for P-4000 Series Polarimeter

## References

1. United States Pharmacopeial Convention: “USP-NF 2024 Issue 3”, (2024).
2. Ministry of Health, Labour and Welfare: June 7, 2021, MHLW Ministerial Notification No. 220, “The Japanese Pharmacopoeia 18th edition”, (2021).
3. Council of Europe: “European Pharmacopoeia 11th edition”, (2023).