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ISO/IEC 17025-Certified Quartz Plate Calibration Service -Support for OQ compliance with USP-NF 2024, Issue 3

Introduction

USP-NF 2024, Issue 3 specifies the operational qualification (OQ) requirements for polarimeters, covering items such as temperature control, wavelength accuracy and bandwidth, accuracy of optical rotation, repeatability of optical rotation, and linearity of optical rotation. For the Accuracy of Optical Rotation test, the quartz plates must be calibrated by an ISO/IEC 17025-accredited calibration laboratory that is either recognized by a national metrology institute under the CIPM*1 Mutual Recognition Agreement (CIPM MRA), or accredited by an organization that has signed the ILAC *2 Mutual Recognition Agreement (ILAC MRA).
The JASCO Corporation Calibration Division is ISO/IEC 17025 accredited and provides calibration services for quartz plates fully compliant with USP-NF 2024, Issue 3. In addition to supplying calibrated quartz plates, JASCO Corporation Calibration Division also offers calibration services for quartz plates already owned by customers. This report introduces JASCO's calibration service lineup, the role of calibrated quartz plates in OQ described in USP-NF 2024, Issue 3, and the validation program that streamlines the OQ process.

*1 CIPM: International Committee of Weights and Measures
*2 ILAC: International Laboratory Accreditation Cooperation

Quartz Plate

There are four types of quartz plates available for calibration service. The calibration is performed using the D-line from a sodium lamp.
QPA-211-N (practical standard quartz plate, +2°),
QPA-212-N (practical standard quartz plate, -2°),
QPA-213-N (practical standard quartz plate, +17°),
QPA-214-N (practical standard quartz plate, -17°)

Keywords

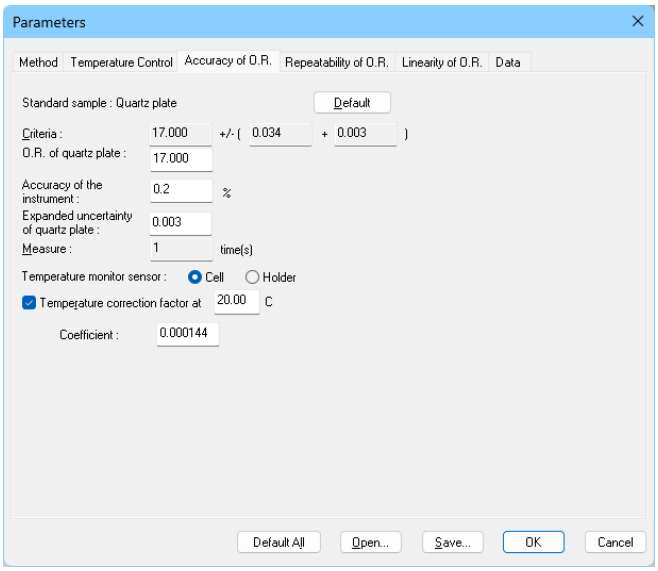
USP-NF 2024, Issue 3, ISO/IEC 17025, quartz plate, calibration service, polarimeter

Repeatability and Linearity

In the Repeatability test specified in USP-NF 2024, Issue 3, the optical rotation for the sample must be measured at least five times, and the standard deviation of the results must comply with the instrument specifications. The quartz plate used for the Accuracy of Optical Rotation test can also be used in the Repeatability test. Furthermore, when quantifying enantiomers using a polarimeter, it is necessary to confirm the Linearity. In this test, the criteria for the Accuracy of Optical Rotation test must be satisfied for at least three optical rotation values within the theoretical range. The same quartz plate used in the Accuracy of Optical Rotation test can also be used for this purpose.

Validation Program

The P-2000 series polarimeters (PC-controlled type) come with a validation program that supports OQ as described in USP-NF 2024, Issue 3.
In the accuracy of optical rotation test, users enter the optical rotation and expanded uncertainty for the quartz plate (as stated in the calibration certificate issued by the JASCO Corporation Calibration Division), along with the accuracy of the device (as specified in the device specifications). The program then confirms that the measurement results for the quartz plate fall within the range of optical rotation values for the quartz plate ± (device accuracy + expanded uncertainty), thereby facilitating the implementation of OQ as described in USP-NF 2024, Issue 3.



Note 1: Implementation of the OQ and the validation program is only possible when using either a sodium discharge lamp or a halogen lamp, both at a wavelength of 589 nm.
Note 2: Wavelength Accuracy and Bandwidth, one of the USP inspection items, is not covered by the validation program. However, in the OQ test, when a sodium discharge lamp is used, the wavelength of the D-line is recorded in the qualification workbook. When a halogen lamp is used, the center wavelength and the full width at half maximum specified in the test certificate for the band-pass filter are transcribed into the OQ workbook. For details, please contact your nearest JASCO distributor.

Conclusion

By using quartz plates calibrated by the JASCO Corporation Calibration Division, tests for accuracy of optical rotation, Repeatability, and Linearity can be performed in full compliance with USP-NF 2024, Issue 3. Furthermore, the validation program enables straightforward execution of the OQ procedures specified in USP-NF 2024, Issue 3.

References

USP-NF 2024 Issue 3 <781> OPTICAL ROTATION