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280-PL-0008

Instrument Management Functions for P-4000 Series Polarimeters

< Key Point >

- Instrument management functions support users in effectively maintaining data reliability.

< Introduction >

Instrument management is crucial for accurate measurements using analytical instruments. Measurements should be performed after ensuring that the instrument is in good condition. P-4000 series polarimeters offer three management functions (daily check, validation, and self diagnosis) to help users carry out effective instrument management and ensure accurate measurements.

Fig. 1. P-4000 series polarimeter

Table 1. Instrument management for P-4000 series polarimeters

Function	What to inspect	Typical uses
Daily check	Light source energy, accuracy of optical rotation	Simple inspection at instrument start-up
Validation	Accuracy, repeatability, and linearity of optical rotation	Monthly comprehensive inspection
Self diagnosis	Hardware condition	Troubleshooting when measurement results are unusual

< Keywords >
Polarimeter, instrument management, instrument maintenance, daily check, validation, U.S. pharmacopeia (USP), European pharmacopoeia (EP), Japanese pharmacopoeia (JP)

< Instrument Management >

- Daily Check

Daily check is a simple instrument management function that inspects the light source energy and the accuracy of optical rotation. These inspections can be performed in just a few minutes, which is convenient for a daily instrument check at start-up. Inspection results are shown in a table in chronological order so that changes over time can be easily observed.

Table 2. Inspection items for daily check

Item	Description
Light source energy	Inspects the intensity of the light source. A decrease in intensity due to deterioration of the light source leads to low accuracy and poor repeatability for optical rotation measurements.
Accuracy of optical rotation	Performs measurements using a calibrated quartz control plate and determines the deviation of the measured value from the calibrated value.

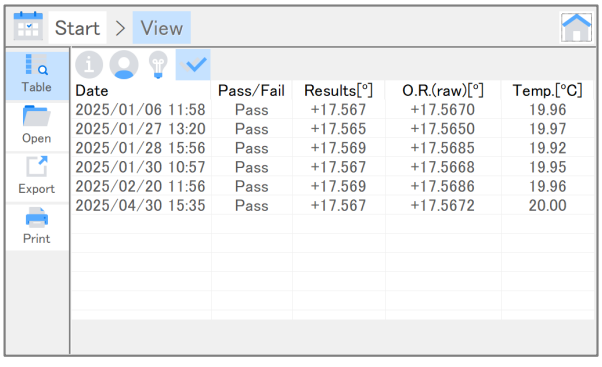

Fig. 2. Result table for accuracy of optical rotation

- Validation

Validation inspects various instrument specifications, such as accuracy, repeatability, and linearity of optical rotation. When a particular pharmacopoeia is selected as the inspection method, inspections that are compliant with the selected pharmacopoeia are performed. When **Basic** is selected, the basic performance of the instrument is inspected. Validation takes two to fifteen minutes depending on the number of inspection items. Therefore, it is used to perform regular comprehensive start-up, weekly, monthly, or annual inspections.

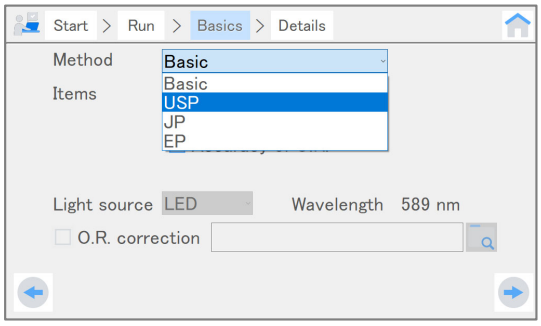

Fig. 3. Inspection methods for validation

Table 3. Inspection methods and corresponding inspection items for validation

Inspection method	Inspection items	Remarks
Basic	Zero repeatability, and accuracy and repeatability of optical rotation	Basic performance of the instrument
U.S. pharmacopeia (USP)	Temperature control, and accuracy, repeatability, and linearity of optical rotation	Compliant with USP-NF 2024, Issue 3
European pharmacopoeia (EP)	Accuracy and linearity of optical rotation	Compliant with EP11.0 (2022)
Japanese pharmacopoeia (JP)	Accuracy of optical rotation	Compliant with JP18 (2021)

- Self Diagnosis

Self diagnosis automatically inspects the condition of hardware such as the light source, temperature sensors, and analyzer motor by a few simple taps on the touch screen. Performing a self diagnosis is recommended when the instrument does not pass the daily check or validation test, or unusual measurement results are obtained.

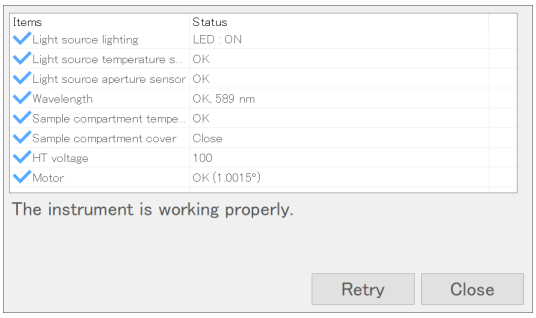

Fig. 4. Self-diagnosis results

< Conclusions >

P-4000 series polarimeters provide three functions for instrument management. These functions support effective instrument inspections, which lead to more reliable data.

Refer to the application note 200-PL-0010 for details about each inspection item for validation.

< Related Application Notes >

- 280-PL-0009 Quartz Plate Calibration Accredited by ISO/IEC 17025
- 200-PL-0010 Validation Compliant to Pharmacopoeia for P-4000 Series Polarimeter

< References >

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

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