Malvern Panalytical
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MORPHOLOGI 4
MORPHOLOGI 4-ID

QUALITY AUDIT STANDARD

CCM0040-01-EN
QAS3007 MEASUREMENT PROTOCOLS
03-2021

Introduction

Malvern Panalytical's QAS3007 Audit Standard has been produced to provide users of the Morphologi 4 and Morphologi 4-ID instruments with a reliable oneshot polydisperse transfer standard to check the performance of their sample dispersion units on a regular basis.

Sample dispersion units are set up at the Malvern Panalytical facility under ideal conditions and are then distributed across the world and used in widely divergent operating environments.

All analytical instruments need to be checked or re-calibrated regularly. A transfer standard such as QAS3007 is the best method of checking whether an instrument is continuing to perform correctly.

In the case of the Morphologi Sample Dispersion Unit (SDU), subtle changes in injection pressure, injection time, sample settling time, cleanliness and wear of the SDU components over time can all have an effect on the unit's performance characteristics. Using a Quality Audit Standard to establish a baseline performance for the SDU and to carry out routine performance checks provides a reliable means of checking and documenting the continued consistency of operation of the unit. This forms part of a user's procedures to meet the requirements of FDA or other international laboratory accreditation schemes (e.g. ISO, NAMAS and IAF).

Compliance with international standards

QAS3007 complies with the particle size analysis validation guidance provided in ISO 13322 (Sect. 11.2). Each single-shot sample consists of spherical particles of known refractive index. In addition, a clear measurement procedure for use of the standard is provided in this datasheet. QAS3007 therefore provides a means of checking and documenting the performance of an imaging system as part of laboratory accreditation schemes (e.g. ISO, NAMAS, and IAF) or in line with regulatory (e.g. FDA, EMA or MHRA) requirements.

Sample Variability

Polydisperse particle sizing standards are prone to segregation during transit, which can lead to sampling errors. To overcome this, Malvern Panalytical's Quality Audit Standards are produced by Whitehouse Scientific Ltd., who have used an extremely efficient riffle-splitting process to ensure that each one-shot sample is representative of the entire batch. Comprehensive sampling of pots taken from the whole production run of the QAS3007 reference material has allowed us to average the data obtained at fixed size percentiles and establish Pass/Fail criteria for the purposes of Performance Verifcation (PV) testing of the SDU. This process has also confirmed that, as long as the entire contents of the bottle are used during a measurement in accordance with the instructions included on this datasheet, reproducible results can be obtained.

Shelf life and batch numbering

Malvern Panalytical's Quality Audit Standards are made of inert glass beads and are stored in sealed containers. They have a shelf life of five years. It has also been possible to provide many years of continuous supply from a single, large master batch. As a result, the only batch number for QAS3007 is 01.

Traceability

These samples are traceable to the UK's National Physical Laboratory (NPL) by a transfer method. They have been characterised on a reference Morphologi instrument which in turn has been verified using a reference slide certified and traceable to NPL. The pass/fail specifications set for Malvern Panalytical's Quality Audit Standards have been developed via a fully documented programme of testing using reference Morphologi instrument which in turn has been verified using a reference slide certified and traceable to NPL. As such, although these standards are transfer standards, they are indirectly traceable to internationally recognised length standards.

Establishing Pass/Fail criteria and measurement procedures

An on-going programme of dispersion unit testing is carried out by Malvern Panalytical in order to characterize each Quality Audit Standard and establish the pass/fail criteria referenced on this datasheet. As testing continues, Malvern Panalytical constantly assesses the average measurement values obtained over the entire population of sample dispersion units. As the population increases, slight adjustments to the pass/- fail criteria may be required in order to make sure that these accurately reflect the expected performance of all units. Changes may also be made to the measurement procedure in order to ensure robust measurements can be made.

Given the above, it is important that the latest version of this datasheet is used, especially when carrying out an annual system OQ or PV. In case of doubt, the latest version number can be obtained by visiting Malvern Panalytical's website. If there is any disagreement between the datasheet and the latest OQ procedure, the OQ certificate and specification should be considered to take precedence over the datasheet.

Morphologi 4
Morphologi 4-ID

Sample Preparation

Dismantle the SDU chamber assembly

Remove the air pipe if fitted. Unclip the SDU chamber from the instrument and unscrew the cap.

Clean the SDU chamber

Clean chamber with anti-static cleaning fluid and clean- room wipe. Allow to dry naturally. It is important that the chamber is completely dry before use. If it remains moist too long (approximately 5 minutes) then blow through with compressed air. Also ensure the red O- ring at the bottom of the chamber is free of particles, clean and dry.

Clean the sample dispersion spool

Clean the metal spool parts with anti-static cleaning fluid and a cleanroom wipe. Allow it to dry naturally before assembling. See the instrument user manual for more information regarding the cleaning process.

Clean glass plate

Check that the SDU glass plate is free from any form of contamination (particularly grease) and is scratch free. If it is greasy, clean with a mild soap solution or alcohol based glass cleaner. Check that the slide is clean and free of dust and dirt. A 'clean-air' aerosol can be used to blow off any dry dust particles as a final step in the cleaning procedure. Fit the glass plate into the XY stage.

Load sample entrainment spool

Tap the QAS3007 sample vial to ensure all material is at the bottom of the vial before opening. Open the vial and tip the contents against the side of the central funnel of the sample dispersion spool, ensuring no material is lost during transfer. Make sure that the entire contents are transferred into the sample holder inside the spool. Tap the vial several times while inverted to make sure all material is transferred to the funnel and none is trapped on the shoulder of the vial. Assemble the spool following the instructions in the instrument user manual. Place it into the top of the SDU chamber, being careful not to tilt or invert the spool.

Load the SDU chamber

Fit the screw on cap to the SDU chamber, ensuring that it is completely tight, as this completes the sealing of the sample spool. Slide the chamber into the SDU arm and attach the air pipe to the top of the chamber cap.

Take a measurement

Select the QAS measurement

Select Measure -> SOP... and select check M4_SDU_QAS_Vx.y.vsop

Perform the measurement

Click on the start arrow to start the measurement. You will be given an opportunity to modify the measurement name. Append the Bottle No of the bottle used for the measurement.

View & Print result

Click on the System CheckM4_QAS_3007_Vx.y.vrep. This report contains custom calculations that will automatically check each parameter is within specification, reports a PASS/FAIL for each parameter and reports an overall PASS/FAIL.

Expected results

QAS3007 is designed for use on the Morphologi Sample Dispersion Unit (SDU). Expected limits can be found in the PV certificate and specification documents. In addition, the QAS3007 PV Report_M4_Vx.y report which is provided within the Morphologi software contains custom calculations that will automatically check each parameter is within specifi cation, and will provide an overall Pass/Fail. The Pass/Fail limits applied within the PV certificate and within the Morphologi report are summarised below:

	Mean / µm	Dn10 / µm	Median / µm	Dn90 / µm
Lower Limit	39.89	26.63	39.06	53.30
Upper Limit	44.94	32.06	44.72	57.30

	Dv10 / µm	Dv50 / µm	Dv90 / µm	No particles
Lower Limit	33.87	47.04	59.07	40,000
Upper Limit	38.81	50.83	62.98	-

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