

MASTERSIZER 3000 **HYDRO EV**

QUALITY AUDIT STANDARD

CCM0059-01-EN

QAS4002 MEASUREMENT PROTOCOLS 2.5g One-shot polydisperse glass bead transfer standard.





Introduction

Malvern Panalytical's QAS4002 Quality Audit Standard has been produced to provide users of Malvern Panalytical laser diffraction particle size analysers with a single-shot, polydisperse transfer standard that enables users to check the performance of their systems on a regular basis.

Compliance with international standards

QAS4002 complies with the laser diffraction system validation guidance provided in ISO13320, USP <429> and EP 2.9.31.

Each single-shot sample consists of spherical particles of known refractive index which have a particle size distribution which extends over greater than one decade in size. In addition, a clear measurement procedure for use of the standard is provided in this datasheet. QAS4002 therefore provides a means of checking and documenting the performance of a laser diffraction 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

Each Quality Audit Standard bottle is filled using a riffle-splitting process which ensures each sample is representative of the entire 5,200 kg master batch. The sample variability (95% tolerance limit) following riffle-splitting has been measured for the QAS4002 Quality Audit Standard via testing using a single reference Mastersizer system and has been confirmed as:

	Dv10 / μm	Dv50 / μm	Dv90 / μm
QAS4002 Sample variability	+/- 0.267	+/- 0.140	+/- 0.280

Shelf life and batch numbering

Malvern Panalytical's Quality Audit Standards are inert and are stored in sealed containers. They have a shelf life of 5 years. They are produced from a single, large 5,200 kg master batch. As a result, the only batch number for QAS4002 is 03.

Traceability

The Quality Audit Standard Pass/Fail specifications have been defined via a documented test procedure using reference laser diffraction systems. These systems have been verified using NIST-traceable polystyrene latex standards. As such, although these standards are transfer standards, they are indirectly traceable to NIST.

Establishing Pass/Fail criteria and measurement procedures

An on-going programme of dispersion unit testing is carried out by Malvern Panalytical to characterize each Quality Audit Standard and establish the target specification. The allowable variation of this target specification is then set taking into account both the sample variability and the expected system measurement variability referenced by ISO13320.

Malvern Panalytical constantly assesses the average measurement values obtained over the entire population of Mastersizer 3000 dispersion units. As the population increases, adjustments to the target specification may be required to make sure these accurately reflect the expected performance of all units. The measurement procedure may also be adjusted to improve the measurement robustness.

Given the above, it is important that the latest version of this datasheet is used. To confirm this is the latest datasheet, visit the Malvern Panalytical website or contact your local Malvern Panalytical representative. If there is any disagreement between the datasheet and the latest OQ procedure for your system, the OQ certificate and specification should take precedence over the datasheet.

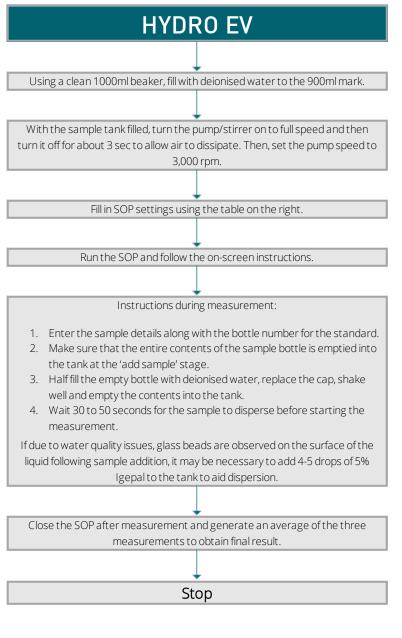
Expected results

The specifications for the Mastersizer 3000 dispersion units are based on guidance from ISO13320 (2020). This standard allows for a maximum instrument uncertainty (u_p) of \pm 1.5% for the Dv50, \pm 2% for the Dv10 and \pm 2.5% for the Dv90. The instrument uncertainty is combined with the sample uncertainty (u_{crm}) according to equation (1) where CF is the coverage factor. As defined in the ISO standard the coverage factor is usually set between 2 and 3 depending on the desired level of confidence. A coverage factor of 2.5 has been selected to provide a confidence level of 99% and to maintain a level of consistency with specifications set under the guidance of the previous edition of ISO 13320.

$$U_{lim} = \pm CF \cdot \sqrt{u_{crm}^2 + u_p^2}$$

Taking into account the instrument, sample variability, and coverage factor the target specification for this sample is as follows:

	Dv10 / μm	Dv50 / μm	Dv90 / μm
Combined sample variability and measurement tolerance	5.08%	3.76%	6.26%
Upper Specification Limit	38.949	74.593	111.201
Target Value	37.066	71.890	104.650
Lower Specification Limit	35.183	69.187	98.099



Sample					
Particle type	Spherical				
	Name	Glass beads (typical)			
	Refractive index	1.52			
Material	Absorption index	0.00			
	Density	2.45			
	Different blue-light properties				
Dispersant	Refractive index	(Water) 1.33			
Measurement					
	Background measurement duration (s)	15			
Duration	Sample measurement duration (s)	15			
	Don't perform blue light measurement	\checkmark			
	Number of measurements	3			
Sequence	Delay between measurement (s)	0			
	Pre-measurement delays (s)	0			
	Obscuration lower limit (%)	10			
	Obscuration higher limit (%)	30			
Obscuration	Auto start measurement, when obscuration is in range				
	Enable filtering				
Sample Disper	sion				
	Stirrer speed (rpm)	3,000			
Accessory	Tank fill behavior mode	Manual			
	Ultrasound mode	None			
	Clean type	Normal			
Classia a	Clean cycles	3			
Cleaning	Ultrasonication	Enable 'No ultrasound during clean'			
Data Processin	g				
Analysis mode	Analysis Model	Narrow modes			
	Single mode	$\overline{\mathbf{Y}}$			
Advanced	Number of inner light detectors to exclude	0			
	Remove blue light from analysis				
	Sensitivity	Enhanced			
	Limit the result size range				
Results	Result type	Volume Distribution (recommended)			
	Extend the result	All options			
User sizes	Use default sizes				

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