

Particle size 

Particle shape 

Morphologi®
G3



Automated Particle Characterization System

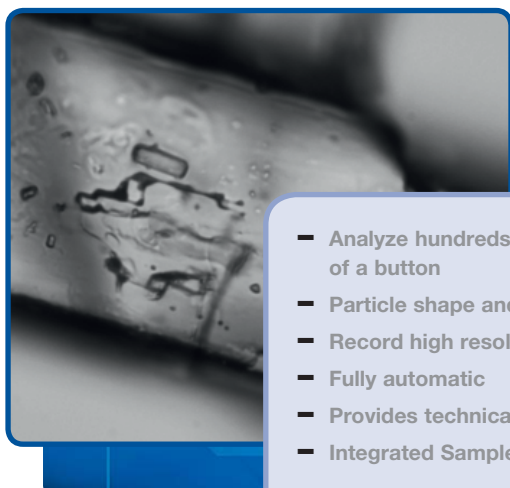
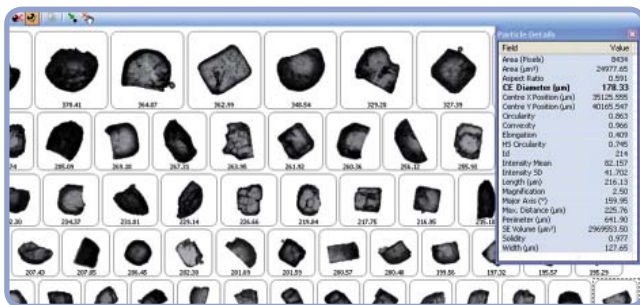
Introducing a new concept in particle characterization

Are you looking for?

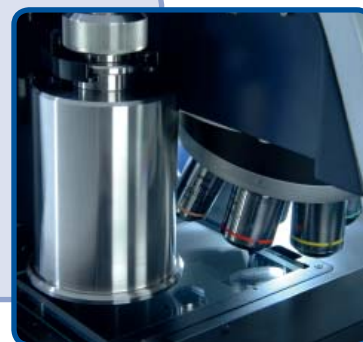
- A fully automated and flexible solution from sample dispersion through to data analysis
- A more detailed knowledge of your particles and how they behave during processing
- A better understanding of your particulate materials from development through to production
- Statistically significant high quality size and shape information in one measurement with minimal user intervention
- A new tool for Quality by Design and PAT
- Saving time and labour automating your microscopy work



Knowledge and understanding of particle shape as well as size is now essential in the development and control of many industrial processes. The Morphologi® G3 particle characterization system from Malvern® Instruments provides high quality, statistically significant particle size and shape information. We have brought together the very best hardware and software in a single integrated package to provide the very highest level of automation and validation of results. Whether you work in R&D, process analysis or quality control, the Morphologi G3 delivers reliable, repeatable and validated results in minutes.



- Analyze hundreds of thousands of particles at the push of a button
- Particle shape and count as well as size information
- Record high resolution images of every particle
- Fully automatic
- Provides technical compliance with 21CFR Part 11
- Integrated Sample Dispersion (G3S)



What Morphologi® G3 delivers

You asked for

We give you

Reliable dispersion of dry powders

A novel, fully integrated, software controlled dry powder dispersion system that reduces sample preparation times and significantly improves the repeatability of measurements. Precise control of dispersion pressure, injection time and settling time ensures highly reproducible measurements across a broad range of samples.

Meaningful data analysis

A powerful software tool to compare and cluster data to find differences or similarities between multiple measurements, allowing the user to make decisions quickly and with confidence.

Repeatability and automation

The tried and tested SOP (Standard Operating Procedure) methodology records all software and hardware variables in a single file. With a single click of a mouse the system then selects and calibrates the required magnification, calibrates the light intensity, focus and scans a defined area.

Sensitivity to shape

Particles that are fully characterized using a number of morphological parameters such as circle equivalent diameter, circularity and convexity. This high quality information can be used to distinguish between materials that appear identical to a conventional microscope or traditional particle sizer.

High quality optics

Nikon's acclaimed CFI 60 optics. To obtain outstanding optical performance we have chosen Nikon's revolutionary CFI 60 optical system which provide longer working distances and high Numerical Apertures (NA), while producing images which are high contrast, extremely sharp and have a minimum of flare.

Statistical significance

Every particle in the sample analyzed, avoiding any sub-sampling and a statistically significant number of particles are captured in seconds or minutes. The number of particles required depends upon the size standard deviation of the sample but typically in the range 5,000 – 500,000.

Images you can see

Particle images that are saved for future reference including the 'xy' coordinates of each particle. If desired, you can precisely move the sample back to any position for a more detailed visual analysis.

Controlled orientation

Consistent particle orientation. Random orientation significantly reduces the validity of data. To avoid this common source of error, particles are dispersed onto a flat glass plate, which has the effect of consistently orientating them with their largest area facing the camera.

Regulatory compliance

The Morphologi® G3 has a full validation documentation package available and provides technical compliance with the requirements of 21CFR part 11.

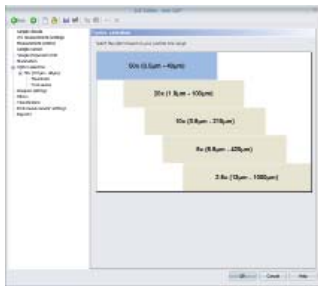
A product and company with a secure future

Recognizing that most of our customers have global operations Malvern® Instruments is committed to providing a service and support structure which is present worldwide and has a high degree of applications knowledge.



Simple Operation

Access to the Morphologi® G3 powerful measurement capabilities is controlled via an equally impressive software interface that makes particle characterization by image analysis entirely straightforward.



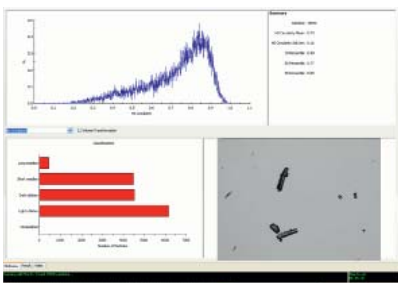
1

Set up your Standard Operating Procedure (SOP) using the system's integrated method definition wizard. SOPs lock-down all aspects of the measurement process to provide repeatable results between measurements and instruments.



2

Run the measurement by selecting the desired SOP from the menu system. This automatically configures the system and ensures everything is optimally set to deliver accurate results. The system will automatically calibrate against a grating and set light intensity and focusing positions.



3

Fully automated analysis with ability to observe each stage of the measurement via the software's measurement manager, if required e.g.: for method development. This allows the user the option to monitor all aspects of the measurement and analysis process.



4

View the results using preconfigured reports. Display distributions and tables. View single particle details in the Particle View or use the Scattergram for easy visualization of measurement data.

Simple sample dispersion

Automated Dry Powder dispersion

- Fully automated sample dispersion
- Reproducible results
- No more user bias
- Safer handling of hazardous substances

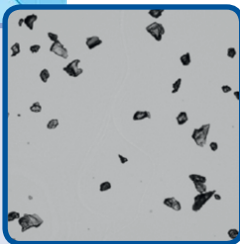
Reliable measurement of dry powders requires strict control of dispersion conditions. A novel, fully integrated, software controlled dry powder dispersion system reduces sample preparation times and significantly improves the reproducibility of measurements.



Samples are loaded in an enclosed sample carrier, minimizing environmental exposure and ensuring safe material handling, especially when measuring pharmaceutical actives or toxic materials samples. Multiple aliquots can be prepared in advance, ready to use at the next measurement.



The sample is dispersed with an instantaneous pulse of compressed air. Precise control of dispersion pressure, injection time and settling time ensures highly reproducible measurements across a broad range of samples.



Flexible Sample Dispersion Accessories

4-slide holder

Measure dry or small particle suspension samples dispersed onto microscope slides on up to four slides consecutively using the Morphologi 4-slide holder



Filter plates

Measure particles captured on filter membranes using the Morphologi Filter plates (25mm or 47mm)



2-slide holder

Measure particles captured on filter membranes sandwiched between glass slides or mounted in a filter petri dish using the Morphologi 2-slide holder



Wet Cell

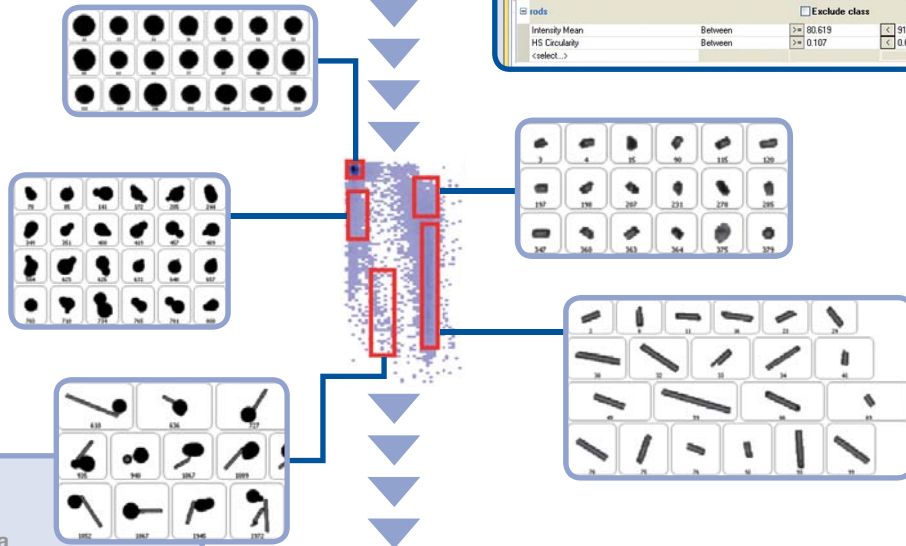
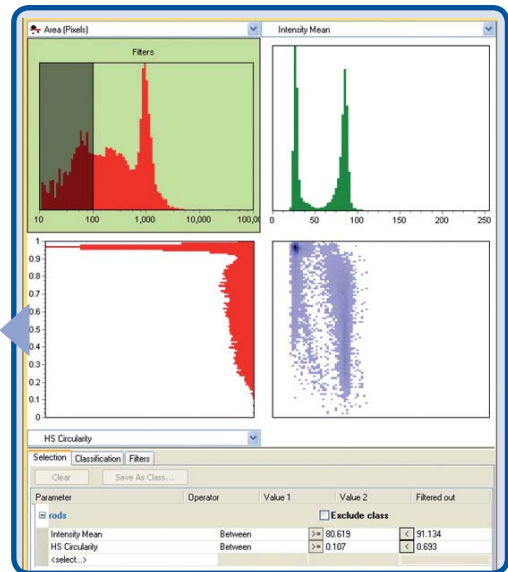
Measure suspended particles in a known volume of liquid using the Morphologi Wet Cell



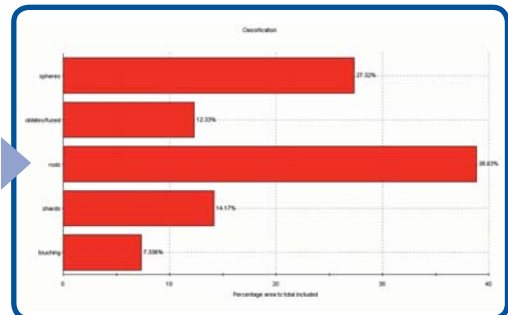
Software to make it happen - Scattergram

Are you looking for?

- Easy access to the most valuable information contained in a measurement.
- Clear visualisation of measurement data
- Easy classification saving time in SOP development



- Visualisation of measurement data
- Plot Scattergrams using any Size/Shape parameter
- Filter on any parameter
- Group and Classify



Apply classifications and filters in order to group or exclude certain particles based on any size or shape parameter.

Software to make it happen - Analyzing data

Are you looking for?

- Quick and easy identification of the most important morphological parameters for differentiating a set of samples such as good and bad batches
- An objective and fast characterization of changes in your product.
- The ability to make the most of the morphological information in every measurement made
- Quantification of subtle changes in your product or process as part of Quality by Design



With the Morphologi[®] G3, lack of data is never a problem, for every particle measured there is a choice of 20 different parameters to describe size and shape. The Morphologi G3 offers a new software tool to compare and cluster data to find differences or similarities between multiple measurements.

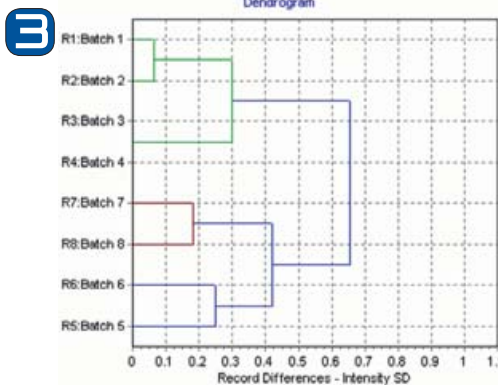
With just a few clicks of the mouse, your data is transformed into useful information, allowing you to make decisions quickly and with confidence.

1 Select the data to compare.

Record	Sample Name	CE Diameter Mean (µm)	Circularity Mean	HS Circularity	Convexity Mean	Elongation Mean	Length Mean (µm)	Mean Intensity
1	Batch 1	58.88	0.938	0.890	0.982	0.125	66.54	60
2	Batch 2	57.64	0.985	0.971	0.993	0.028	59.40	60
3	Batch 3	49.92	0.987	0.973	0.994	0.022	51.41	61
4	Batch 4	49.92	0.987	0.973	0.994	0.022	51.41	61
5	Batch 5	48.67	0.976	0.952	0.984	0.019	50.11	56
6	Batch 6	47.91	0.981	0.962	0.990	0.023	49.40	56
7	Batch 7	57.42	0.986	0.973	0.993	0.022	59.09	57
8	Batch 8	49.57	0.984	0.968	0.992	0.022	51.10	56

- ### 2
- CE Diameter (µm)
 - Length (µm)
 - Width (µm)
 - Max. Distance (µm)
 - Perimeter (µm)
 - Area (µm²)
 - SE Volume (µm³)
 - Circularity
 - HS Circularity
 - Convexity
 - Solidity
 - Aspect Ratio
 - Elongation
 - Intensity Mean
 - Intensity SD

The software will automatically calculate the difference for each parameter, highlighting the most significant one.



Measurements can then be clustered into different groups based on the parameter showing the biggest difference.

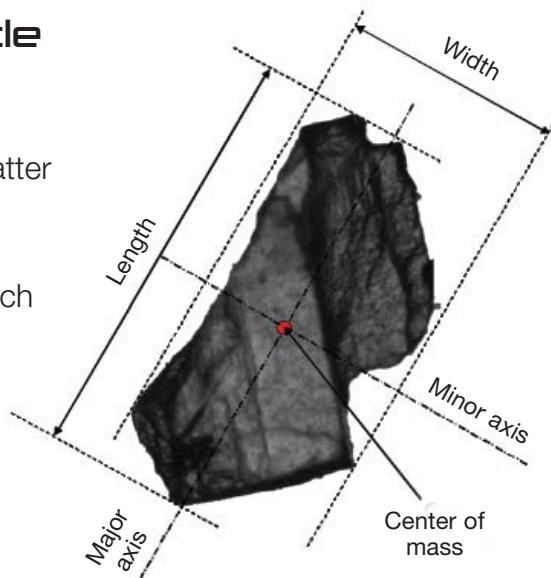


The trend plot will indicate a suitable QC parameter to distinguish between good and bad batches.

What is particle size and particle shape?







Describing a 3D particle is often a more complex matter than it first appears. For simplicity it is convenient to describe particle size as one single number. However, unless the particle is a perfect sphere (which is rare in 'real-world' samples) there are many ways to describe the size of a particle.

Image analysis systems capture a 2-dimensional image of the 3D particle and calculate various particle size and particle shape parameters from this 2D image.

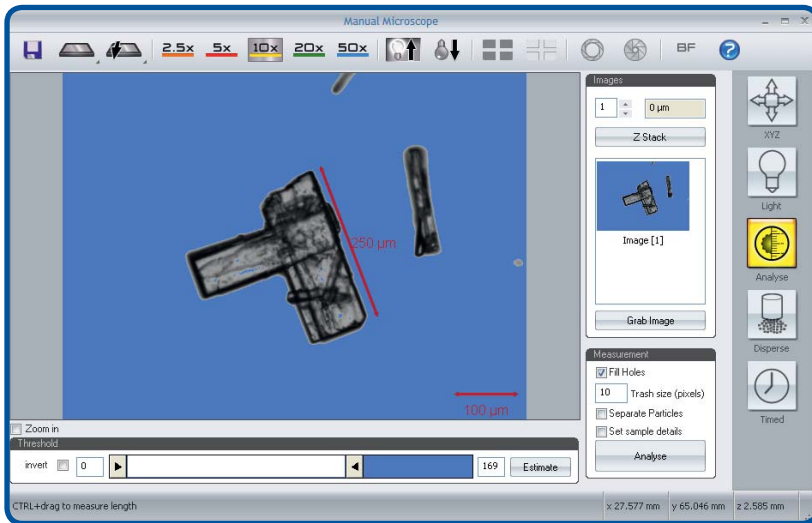


Why is shape analysis important?

Shape parameters such as Circularity, Convexity and Elongation provide the user with a series of highly sensitive tools in order to identify and quantify subtle variations in particle shape and provide a “fingerprint” of each sample. Each parameter is usually normalized between 0 and 1 in order to provide quick and easy comparability. Traditional qualitative human descriptions such as “jagged”, “smooth” or “needlelike” can be accurately quantified and hence correlated against important process or end-product variables such as flowability, active area and grinding efficiency.

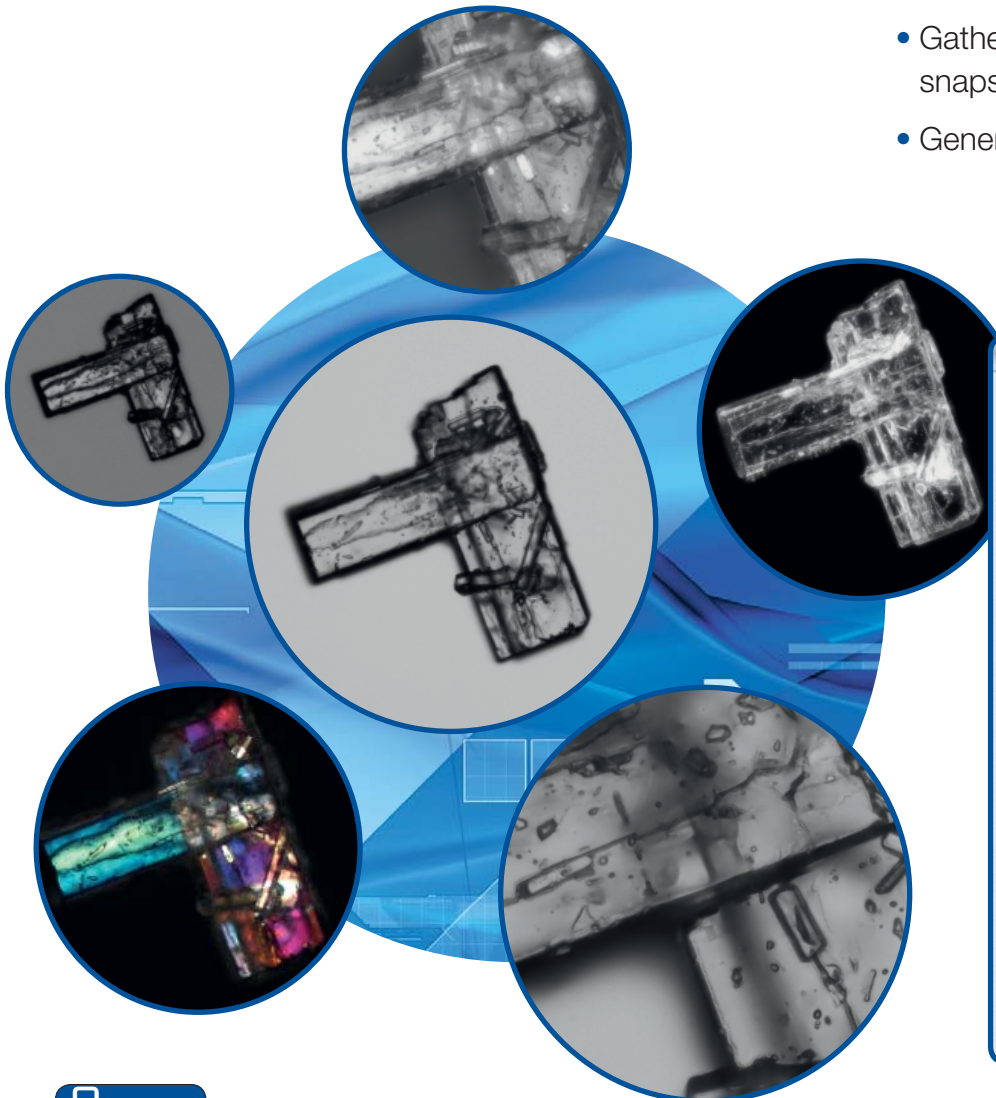
						
Circularity is a measure of the closeness to a perfect circle. Circularity is sensitive to both changes in overall form and edge roughness.	Circularity = 1	Circularity = 0.64	Circularity = 0.89	Circularity = 0.67	Circularity = 0.50	Circularity = 0.35
Convexity is a measure of the edge roughness of a particle. Convexity is sensitive to changes in edge roughness but not overall form.	Convexity = 1	Convexity = 0.96	Convexity = 1	Convexity = 1	Convexity = 0.59	Convexity = 0.69
Elongation is a measure of the length-width relationship. Elongation is unaffected by edge roughness – a smooth ellipse has a similar elongation to a spiky ellipse of similar aspect ratio.	Elongation = 0	Elongation = 0.82	Elongation = 0	Elongation = 0.79	Elongation = 0.24	Elongation = 0.83

Get more from Microscopy



The Morphologi® G3 offers a flexible microscopy interface allowing the user to:

- Examine specimens using different magnifications and lighting conditions including episcopic, diasopic, bright-field, darkfield, with polarisers, in grey scale or color.
- Capture one or more frames of interest and immediately analyse them.
- Gather timed series of snapshots.
- Generate Z-stacked images.



Particle Details	
Field	Value
Area (Pixels)	476372
Area (µm ²)	36683.62
Aspect Ratio	0.829
CE Diameter (µm)	216.12
Centre X Position (µm)	27561.363
Centre Y Position (µm)	65019.930
Circularity	0.692
Convexity	0.863
Edge stitched particle	0
Elongation	0.171
H5 Circularity	0.479
Id	1
Intensity Mean	86.908
Intensity SD	50.622
Length (µm)	297.27
Magnification	1.00
Major Axis (°)	24.54
Max. Distance (µm)	298.54
Perimeter (µm)	979.66
SE Volume (µm ³)	5285330.50
Solidity	0.777
Width (µm)	246.33

High quality hardware means high quality images

The Morphologi® G3 is built upon the acclaimed Nikon CFI60 optical system which achieves both higher Numerical Apertures (NA) and longer working distances than ever before. Both axial and lateral chromatic aberration have been corrected producing images that are crisp and clear with high contrast and minimal flare.

A precision XY stage provides smooth, maintenance-free motion with zero backlash. A precision etched calibration grating embedded in the stage, certified and traceable to the National Physical Laboratory, ensures that data is precise, accurate and validated for at all times.



Applications and case-studies

At any point in your manufacturing process from early research and development, through process-analysis, manufacturing trouble-shooting and root-cause analysis to final product quality control, this instrument gives you an unprecedented level of product and process understanding.



Even subtle differences in particle size or shape can significantly affect the mechanical strength, bioavailability, flowability, solubility, stability, blending or tableting efficiency. Manufacturing processing steps including atomisation, crystallisation, drying, milling, blending and filtering can all introduce variability into the product and have to be precisely controlled. The extra sensitivity and resolution available in the Morphologi G3® instrument provides users with the ability to identify, measure and monitor those process variables which are critical to the product quality.

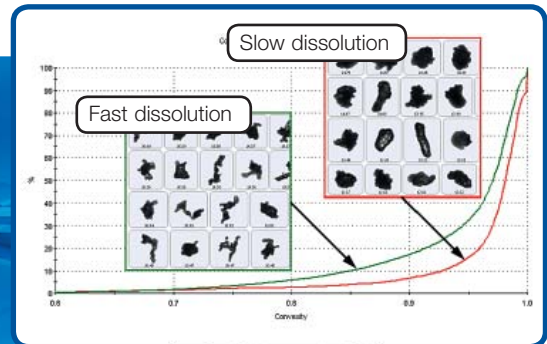
Industrial Examples



Pharmaceutical

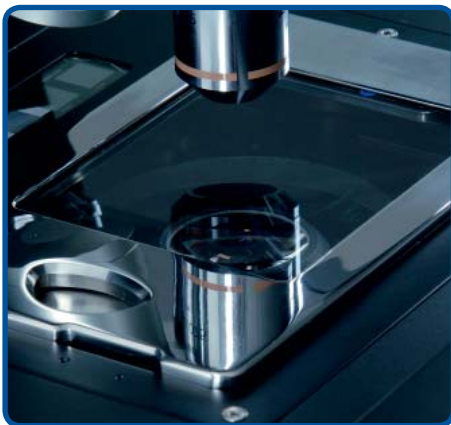
Two batches of the same active material may have the same size distribution but present different solubility profiles.

Comparing the convexity distributions shows that one batch presents a lower convexity, indicating rougher edges and therefore a greater surface area which would explain its faster dissolution.



Measuring Suspensions

The Morphologi® G3's Wet cell accessory allows a known volume of suspended sample to be analysed. For example, the shape of the Gypsum particles, a common mineral used in industries such as building and construction, food additives and agricultural fertilizers, may influence the mechanical properties of the final product. Gypsum is often used in a slurry form so it is preferable to measure it wet.



Foreign particle detection

The Morphologi G3® equipped with its filter holder accessory allows rapid automated analysis of filters free from human subjectivity or bias and provides an electronic image of the filter to be retained for archiving. Several industry standards such as ISO 4407 (automotive) and USPs 788 and 789 (Pharmaceutical) describe the use of microscopy for counting particles collected on a filter. In Hydraulic Systems, particulate contamination is a primary cause of wear-related damage and machine failure.

In Pharmaceuticals contaminant particles might present serious health implications such as blockage of blood vessels, inflammatory or allergic reactions.



Overview

Morphologi® G3/G3S

Size, shape and count measurement of particulate samples

Size measurement

Size range 0.5µm - 10mm
(depending upon material properties and dispersion conditions)

Shape measurement

Multiple shape parameters calculated for each particle and distributions generated on each parameter. Parameters include: Circle equivalent diameter, Length, Width, Perimeter, Area, Aspect ratio, Circularity, Convexity, Solidity, Elongation, Intensity.

Optical configurations

Optical system	Nikon® CFI 60 Brightfield/Darkfield system				
Magnification (at camera)	2.5X	5X	10X	20X	50X
Approximate total magnification (at 17" screen)	123X	247X	494X	987X	2468X
Min particle size (µm) nominal	13	6.5	3.5	1.75	0.5
Max particle size (µm) nominal	1000	420	210	100	40
Numerical aperture	0.075	0.15	0.30	0.40	0.55
Focal depth (total) (µm)	97.78	24.44	6.11	3.44	1.82
Working distance (mm)	8.80	18.00	15.00	13.00	9.80

Camera system

Camera type	1/1.8" Global shutter, progressive scan/interline transfer colour CCD				
Connection protocol type	IEEE 1394a (Firewire™)				
Number of pixels	2592 x 1944 (5 MegaPixel)				
Pixel size	2.78µm x 2.78µm				
Sensor size	7.20mm x 5.40mm				

Sample Dispersion Unit

Morphologi® G3S only;
Integrated Sample Dispersion Unit for the analysis of dry powders. With software control of dispersion pressure, injection time and settling time. Automatic operation via standard operating procedures, manual operation via computer on-screen operating dialogue.
Requires, but does not include, a clean dry compressed air supply.

Accessories

4-Slide holder, 2-Slide holder, 25mm Filter holder, 47mm Filter holder, Wet cell.

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