PTG-S5

Automated Powder Flow Analyzer

The PTG-S5 automated powder flow analyzer is used to measure the flow behavior of granules and powders in compliance with the EP <2.9.36>, EP <2.9.16>, USP <1174> Pharmacopoeia and ISO 4324 standards. This instrument determines the powder flow time, the powder cone angle of the collected powder mound, the weight, the density and the volume of the powder cone. Furthermore, the EP "flowability" result is calculated by measuring the flow time of 100g of sample through a specified pouring nozzle.

The PTG-S5 is equipped with a clear view dust hood, made from anti-static material, to protect the user from most of the dust during the powder analysis. This hood can easily be opened or removed completely for cleaning. The instrument is operated using a large color touch screen.

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Why Measure the Flow Properties of Powders?

It has been estimated that over 50% of the materials used in all industrial applications were at some stage in a powder form. These powders need to be transported, injected, propelled and be able to pass through various process stages before they achieve their final form. This final form may be a tablet, a suspension or indeed a powder formulation. The need to be able to measure, control or test for reproducible powder flow has been well established in many industrial applications.

Powder flow characteristics are important for:

- Reduction in cost of raw process materials: reject bad batches before processing
- Maintenance of the optimum formulation for the process concerned
- Reduction in process costs
- Maintaining the quality and consistency of the final product
- Maintaining process efficiency and costs by optimization of product storage, packing, handling and transportation
- Maintaining powder quality from different suppliers or from the same supplier over a long time period
- Development of new processes where powders are required to be formulated into end products
- Checking moisture effects: use of powders in open systems in different climates
- Investigating and maintaining the quality of dry mixes

In processes, which rely on powder and / or powder, mix integrity, the need to have the correct powder flow characteristics is paramount. These powder mixes have to be formulated, mixed and certainly transported. Transportation, even over small distances an easily lead to classification of sorts such that “fines” may drop out and alter the particle size distribution and hence the flow characteristics.

For example, we can look at formulated mixtures, which are fed into tableting machines: these powders need to flow in exactly the same way from batch to batch. Generally, the active ingredients are materials that have no natural flow properties. They are sticky (cohesive) and prone to agglomeration. Additionally, the requirement of active material in ever decreasing dosages means that the active must be able to be dispersed in a non-active medium (normally made up of well-established and mainly natural products) in a reproducible way in the mixers prior to the introduction of the formulation into the tablet press. The fact that the non-active materials such as MCC (Micro Crystalline Cellulose), starch and lactose are natural products means that these materials are prone to variations in particle size, agglomeration, surface area, and so on, depending on the product source. Then we have to consider the effect of the introduction of materials such as silica (e.g., Aerosil 300), which aid the flow of these normally quite stubborn powders. The need to control each of the components as well as the final mix now becomes clear. Control of this type can save a lot of time, wasted money and resources if checks are made at the right time on these component powders.

Areas Where Powder Flow Characterisation is Commonly Used

Area	Use for Powder Flow Characterization
Pharmaceuticals	Granulation, micronizing, tablets and other solid dosage forms
Abrasives	Ceramics, metallic powders and grinding pastes
Catalysts	Powders for extrudates, catalyst rings, and finely divided metals
Chemicals	Bulk chemicals, fine chemicals
Printing	Pigments, toners and binders
Washing Powders	Powdered surfactants, bulking agents and granulates
Fertilizers	Extrudates, granulates, powdered pesticides

Operating Principle of the PTG-S5

The PTG-S5 is widely used to compare batches of powders perhaps supplied by the same manufacturer over a period of time or for similar materials provides by different suppliers. The flow characteristics can be easily and quickly determined as a QC tool for inter- batch reproducibility, as this may have a distinct bearing on the ease of production especially if powders are capable of agglomeration and cohesion over time.

The design is compliant to the ISO 4324 (12/83) standard, EP <2.9.36>, and USP <1174>. A conical funnel, which can be equipped with different pouring nozzles, takes the sample to be tested. A built-in analytical Sartorius balance cell takes the product-collecting dish. The PTG-ER electrical stirrer may be used for powders, which do not flow well. Most pharmaceutical material contains such a high amount of fine particles that it will not start to flow without assistance.

Enter product information using the alphanumeric keyboard of the instrument. Select the test program you want to use:

- Flow time
- Cone angle
- Volume
- Flow-chart
- Density
- Flowability

Then start the test. Depending on the powder, the PTG-ER stirrer may be used. When the test is started, the funnel is opened and two IR sensors detect the powder flow, this will start the timer to measure the flow time and to record the flow chart. The product itself is collected on a 100mm diameter dish and forms a cone. Once the powder flow stops, the funnel is closed and the movable measuring arm, which holds the two infrared sensors, starts to measure the height of the cone up to the tip. Since the surface of the collecting dish is completely filled, the cone angle can be calculated and displayed.

The test should be repeated (in accordance to the ISO 4324 five times) and the deviation of results should not exceed 5%. The test results are displayed on the color touch screen display of the PTG-S5.

A test report and powder flow-chart will be printed including descriptive information of the product. The report is printed either via the built-in thermal printer or using any Microsoft Windows compatible printer connected directly to the instrument by USB or through a network.

To measure the flowability as per EP <2.9.16> and USP <1174> Pharmacopoeia the test is automatically stopped as soon as 100g of sample have been collected inside a plastic beaker. In addition to the flowability factor (100g/t) the powder flow chart can be printed.

The standard instrument comes with all attachments to measure flow-time, cone angle and flowability in compliance to the current EP/USP Pharmacopoeia. Different pouring nozzles from 4 - 10 mm can be used to test the product. A stirrer can be used to force non-flowing product through the selected pouring nozzle.

The PTG-S5 powder testing system includes a built-in analytical Sartorius balance cell, which extends the instrument use to test powder flowability, density and volume. Additionally, a graph can be plotted on the built-in printer showing the flow behavior of the sample under test.

Using the conical stainless steel funnel as described in the current EP/USP monograph and use the changeable nozzles of 10, 15 and 25mm, the cone angle can also be tested. If smaller diameter nozzles are to be used, an adapter ring, which allows the use of pouring nozzles from 4 to 10mm, is available.

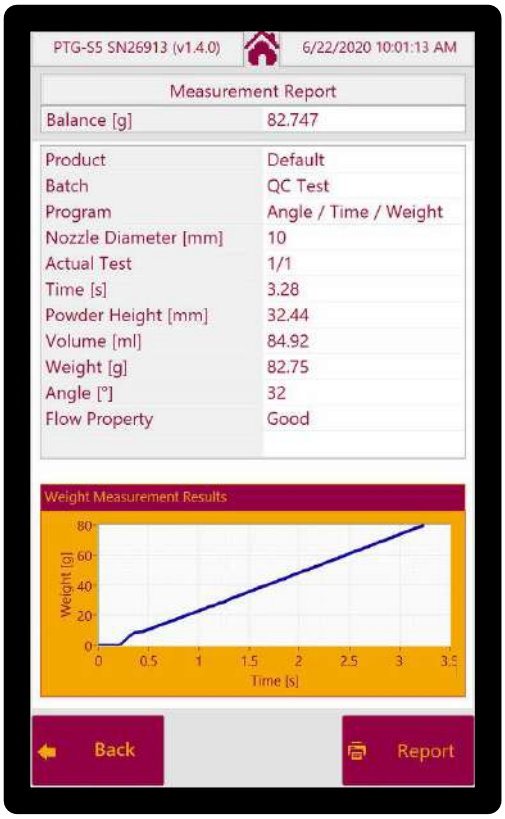
The data and results are displayed on the color touch screen, are stored in a database and can be documented as hard copy print-outs using either the integrated protocol printer or an external printer connected by USB or LAN.

User Interface

PTG-S5 includes a sophisticated user interface using a large integrated color touch screen.

Log on to the instrument by selecting your user from the list and by entering your password. You can either use the on screen keyboard or you can connect any standard USB keyboard to the instrument to enter your data. Depending on your access level, you can log on with different authorization levels. This access authorisation level determines which menus displayed and which settings can be changed.

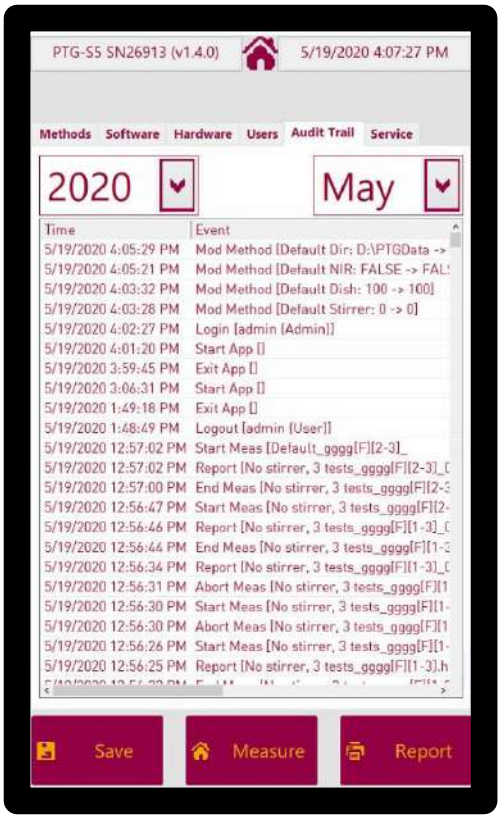
This is the method definition menu. You can enter the tested product and determine the testing parameters. The creation date and the username who created this method displayed here. In addition, you can check when the last change occurred and who made the change. All individual changes are logged in the audit trail. Furthermore, the method menu also shows who last ran a test using this method.



The test results are displayed on screen and can be recalled at any time from the integrated result database. The results are expressed numerically and graphically. Furthermore the flow behaviour is evaluated according to the USP/EP criteria.

You can create additional users directly on the instrument and assign authorisation levels to them. For each user you can see when he was created or modified and by whom. You can also see when last logged in and any failed login attempts as well. It is possible to automatically lock a user account after a certain number of failed login attempts.

It is also possible to determine the minimum length of the password and how often the user has to change it. Furthermore guidelines for secure passwords can be enforced by the administrator.



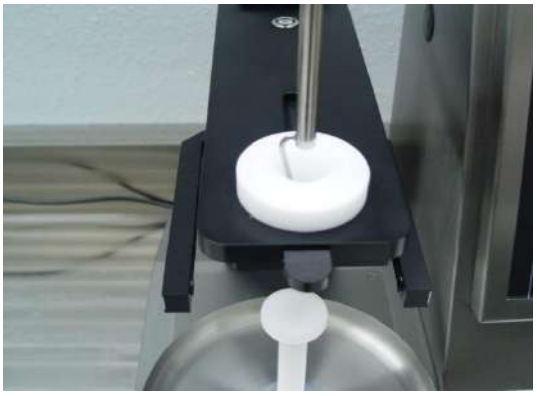
A detailed audit trail shows any event in the application. This can be filtered by date.

The instrument also features a service menu that allows to test the components and sensors of the system. You can check the interal system temperature, power consuption of major components and the inclination of the instrument using an integrated sensor.

Testing Smaller Volumes

For smaller volumes, a 10ml funnel and a smaller sample-collecting dish are available.

This optional accessory can be used with pouring nozzles from 4 to 10mm diameter. A suitable stirring shaft completes the set.



The PTG-S5 Analysis

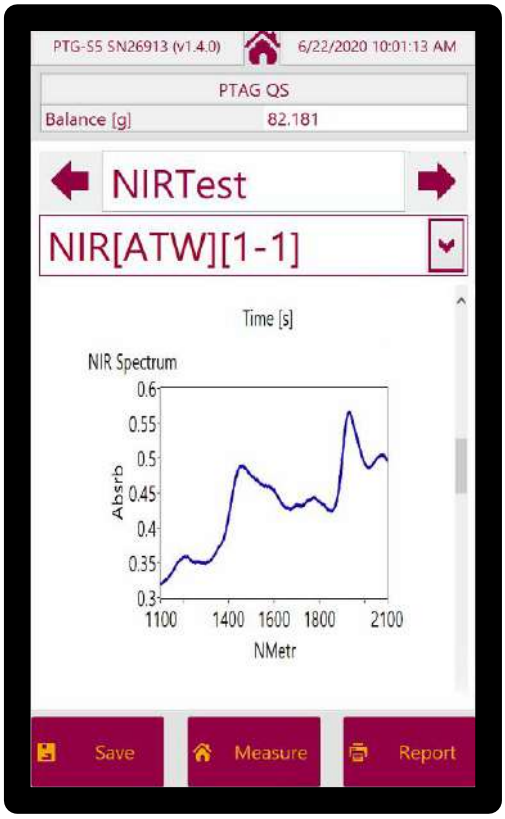
The PTG-S5 determines the following results:

- Powder flow time of a pre-defined mass
- Powder cone volume
- Powder cone density
- Cone angle (angle of repose according to EP <2.9.36>, USP <1174>)
- Flowability of 100g of product (according to EP/DAB <2.9.16>, USP <1174>)
- Amount of sample (mg in a preset time)
- Flow chart of sample (mg/time)

PTG-NIR Option

The PTG-NIR automatic powder and granule analysis system combines the Pharma Test PTG-S5 powder flow testing instrument with an integrated J&M TIDAS L NIR diode array spectrometer.

The system is controlled by the powerful TIDASDAQ3 software including a customized script for the PTG-NIR. The system is ideal to examine the flow characteristics of a powder or granule. This combination is ideal for simultaneous detection of chemical, physical and morphological information. This information is describing the flow behaviors of a powder or granule. Other forms of solids are possible to be tested too. All the results are presented in a single report.



By adding the NIR spectrometer the range of application is expanded for the additional analysis of:

- Moisture content
- API concentration
- Qualitative “finger printing” of powder content
- Homogeneity of blended components

Advantages

» Reduce process costs
» Improve product consistency from batch to batch
» Keep tight control of component powders, especially if they are natural products
» Compare sources of powdered products
» Provides an easy method to achieve quality control on bulk incoming component products
» Provides an easy method for the control of dry and wet mixing, tableting, granulating, and capsule filling
» Predict powder transport through conveyors, air lifts and in silos
» Predict powder suitability for capsule and bottle filling
» Predict product settling during transport, so called classification
» Predict powder influence on tablet hardness and solid dosage form stability
» Predict powder influence on tablet disintegration and friability
» Integrated clear view dust protection dust protection hood

Features

» Fully USP <1174>, EP <2.9.36>, EP <2.9.16 and ISO 4324 (12/83) compliant
» Measure flow-time, cone angle, flowability, cone density and cone volume
» PTG-ER stirrer included
» Integrated analytical balance cell
» Integrated dust protection bonnet
» Built-in printer

Standard Scope of Supply

The PTG-S5 comes ready to use with the following standard scope of supply:

» PTG-ER automatic stirrer
» Integrated clear view dust protection hood
» Integrated Sartorius balance cell
» Poring nozzles size 6, 8, 10, 15, 25mm
» 600ml beaker
» 30° angle calibration cone (calibration certificate optional)
» Comprehensive documentation folder including:
  › User manual
  › DQ/QC instrument compliance test certificate
  › IQ documentation
  › OQ documentation
  › Instrument logbook
  › Compliance certificates for vessels and stirring tools

Options

In addition to the standard scope of supply, Pharma Test offers a broad range of accessories and options including:

» 10ml small volume test set, includes POM funnel, stirrer, sample collecting dish, validation cone
» Hand scoop to fill in powder
» Full range of certified validation tools available

Example Print-Out of a Test Report

This is an example of a test report from the internal printer. It is also possible to print on a connected, large paper printer:

Test Report
PTG-S5 (v1.4.0)
S/N : 26913

5/15/2020 1:07:16 PM

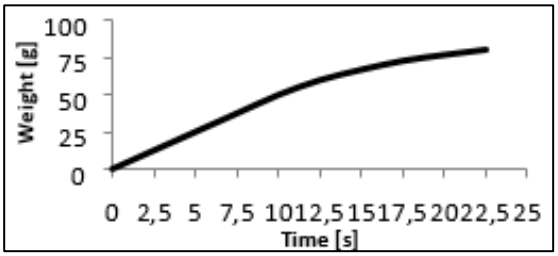
SETTINGS

Product	Stirrer, 3 tests
Batch	1234abcd
Program	Angle/Time/Weight
Nozzle Diameter [mm]	10
Actual Test	1/3
Powder Volume [ml]	100
Dish Diameter [mm]	100
Stirrer Speed [RPM]	25

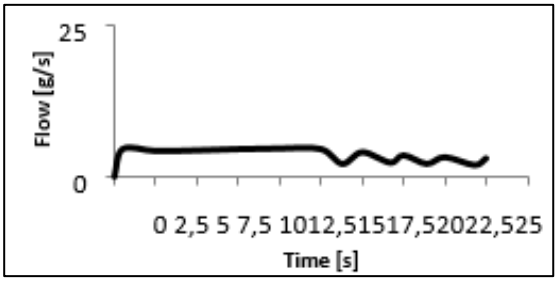
RESULT

Time [s]	7.38
Powder Height [mm]	27.82
Volume [ml]	72.84
Weight [g]	180.91
Angle [°]	29
Weight [g]	80.53
Flow Property	Excellent

Weight Measurement Results



Flow Stability



Performed by user:

_____

Approved by:

_____

The report header logo is customizable and can be exchanged for your company logo for example.

Type of the instrument (PTG-S5) and firmware version
Serial number of the instrument

Date and time of this print out

Product description entered during method creation
Batch number entered at the start of this test
Active test programs
Nozzle sized used
Number of runs to be performed
Powder volume used for test
Type or receiving dish used
Rotating speed of the PTG-ER stirrer

Results obtained
Total time in seconds
Powder cone height in millimeter
Volume of the powder in milliliter
Angle of Repose in degrees
Evaluation of flow property according to Pharmacopeia

Weight over time chart

Stability of flow chart

Signature line for operator

Signature line for approval

Technical Data

Parameter	Specification
Display	7", high resolution color LCD, backlit
Data Entry	Touch screen, USB keyboard optional
Instrument Firmware Compliance	21 CFR Part 11 compliant user management and result database, integrated audit trail
Method Storage	Integrated database
User Management	Integrated database
Result Storage	Integrated database
Cone Volume	Approx. 450ml
Cone Material	Stainless Steel
Range for Cone Angle Test	1.0° to 65.0°
Range for Flowability Test	0.1 sec. to 999 sec. - mass: 100g
Range for Flow Time Test	0.1 sec. to 999 sec.
Range for Cone Density	0.000g/ml-1 to 6.0g/ml-1
Range for Cone Weight	1mg to 325g
Range for Cone Volume	0.1ml to 275ml
Interfaces	USB, LAN
Printer	Built-in thermal printer, option to connect USB or LAN printers
Instrument Housing	Stainless steel to meet GLP requirements
Instrument Dimensions	Approx. 50cm x 55cm x 90cm (width x depth x height)
Packaging Dimensions	Approx. 90cm x 67cm x 80cm (width x depth x height)
Net / Gross Weight	Approx. 35 / 50 kg
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.