

### PTG-S4 – Automated Powder Flow Analyzer



The automated PTG-S4 powder testing system is used to measure the flow behavior of granules and powders in compliance with the EP <2.9.36>, USP <1174> Pharmacopoeia and ISO 4324 standards. This instrument is suitable for testing powder flow time, the measurement of the cone angle of the collected powder mound, measuring the weight, calculating the density and the volume of the powder cone as well as the EP "flowability" results which is measures the flow time of 100g of sample through a specified pouring nozzle. The PTG-S4 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 and removed for cleaning.

#### 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
- And many other reasons

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.

#### **Common Areas of Use for Powder Flow Characterisation**

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-S4**

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 those powders, which do not flow due to the high percentage of fines.

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 possibly the PTG-ER stirrer, is needed as most of the pharmaceutical material has such a high amount of fine particles that it won't start and flow without any assistance. When the test is started the funnel is opened and two IR sensors detect the powder flow, this will start the timer to measure Flow Time and to record the Flow Chart. The product itself is collected at a 100 mm diameter dish and forms a cone. If there is no more powder flow the funnel is closed and the movable measuring arm which holds the two infra-red sensors starts to measure the height of the cone up to the tip. As 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 at the LCD display of the PTG-S4. Using the built-in thermo printer a test report and powder flow-chart will be printed including descriptive information of the product.





To measure the flowability as per EP <2.9.36> and USP <1174> Pharmacopoeia the test is automatically stopped as soon as 100mg of sample have been collected inside a suitable plastic beaker. In addition to the flowability factor (100mg/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-S4 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 shall be used we supply an adapter ring which allows the use of pouring nozzles from 4 to 10mm.



Up to 10 tests can be done and used to calculate statistics including mean values of all selected test parameters. The data and results are displayed at the LC-display, presented as hard copy on the built-in printer or transmitted via RS-232 interface to any external data collection system.



This instrument 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.





# **Test 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-S4 Analysis

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

#### **Instrument Qualification Program**

The PTG-S4 features and in-built qualification program to:

- Validate the angle measurement
- Validate the timer
- Set current time and date
- Show actual firmware version installed

#### **Advantages**

Some of the highlights the PTG-S4 offers are:

- 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**

The main features of the PTG-S4 are:

- Fully USP <1174>, EP <2.9.36> 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-S4 comes ready to use with the following standard scope of supply:

- PTG-ER stirrer
- Integrated clear view dust protection hood
- Integrated Sartorius balance cell
- Integrated thermo printer
- Pouring nozzles size 6, 8, 10, 15, 25mm
- 600ml beaker
- 30° angle calibration cone
- Comprehensive documentation folder including:
  - User manual
  - IQ documentation
  - OQ documentation
  - Instrument logbook



### **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





# **Technical Data**

Parameter	Specification
Display	LCD
Data entry	Alpha-numerical keyboard and function keys
Data entries	12 digit product code 12 digit batch number
Volume of the stainless steel cone	Approx. 450ml
Range for cone angle test	1.0° to 45.0°
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 <sup>-1</sup> to 6.0g/ml <sup>-1</sup>
Range for cone weight*	1mg to 325g
Range for cone volume*	0.1ml to 275ml
Interface	RS232 serial interface
Printer	Built-in thermo printer or external parallel printer port
Instrument housing	Stainless steel to meet GLP requirements
Packaging dimensions	Approx. 90 x 34 x 80cm
Net weight	Approx. 35kg
Gross weight	Approx. 50kg
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

