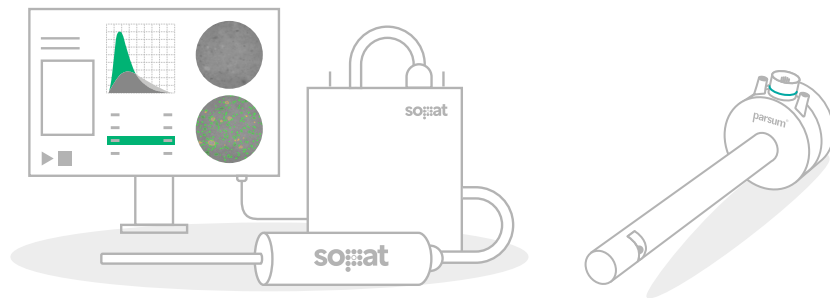


# Inline particle technology for the pharmaceutical industry

Discover our photo-optical inline technology

MADE IN GERMANY



parsum®

so:at

# Inline analysis in the Pharmaceutical Industry



## IN THE PHARMA INDUSTRY

**Building quality into pharmaceutical processes is the leading purpose of the Process Analytical Technology (PAT) initiative.** Particle size is a critical quality attribute in a number of pharmaceutical unit operations such as emulsification, coacervation, crystallization, suspensions, granulation, spray drying and pelletization. An adequate particle size distribution (PSD) is essential to ensure the end product's safety, efficacy, and quality. Therefore, monitoring and controlling particle size via inline measurements is essential to the pharmaceutical industry.

## SOPAT & PARSUM

A solution for the entire Pharma spectrum

With the SOPAT inline probes for the wet in-situ applications like crystallization, emulsification, coacervation and the **Parsum IPP 80-P probe for the dry in-situ applications like granulation, spray-drying, pelletization**, we are able to address the inline measurement needs of the entire pharmaceutical application spectrum.

## QUALITY BY DESIGN (QBD)

**With SOPAT & Parsum, the user can significantly reduce operational costs through significant increases in throughput and productivity** by reducing off-specification batches and continuous monitoring of CQAs (Critical Quality Attributes). Falling inline with the Quality by design approach in manufacturing of pharmaceuticals, we aim in enhancing the safety and efficacy of drugs being delivered to the consumer.

## COST-BENEFIT RATIO

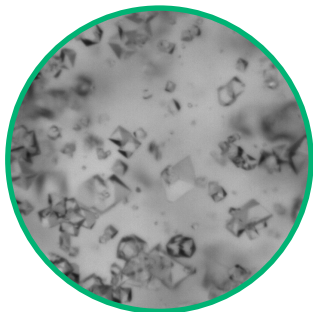
Continuous monitoring of particle size distribution increases process transparency, shortens response times in the event of process disturbances, makes continuous quality control possible, precludes charging errors, **avoids the need to spend time and money on transporting samples and laboratory analysis.** The cost savings are produced not only by the saving on time for laboratory analysis but also by direct prevention of batching errors, remedial work, recycling volumes and the benefits of optimized process control.

## The solution

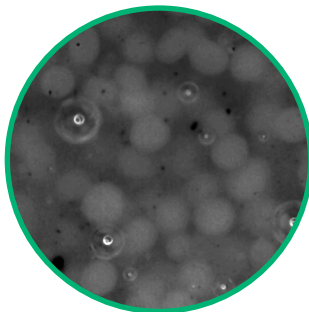
**so:at**



**parsum**<sup>®</sup>



**Crystallization**



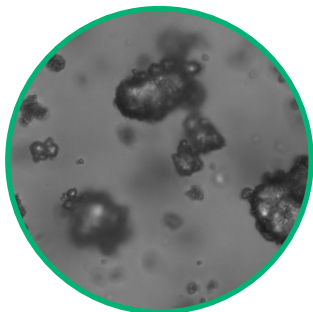
**Microspheres**



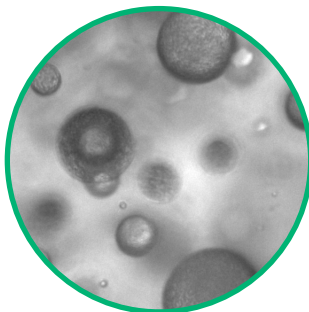
**Extrusion**



**Fluid bed granulation**



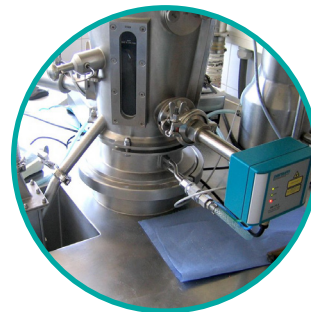
**Suspensions**



**Emulsions**



**Spray drying**



**Pelletization**

**and many more ...**

# Technology meets innovation



One stop-shop for all your inline measurement needs in pharmaceutical processes

## IMAGING

### Imaging:

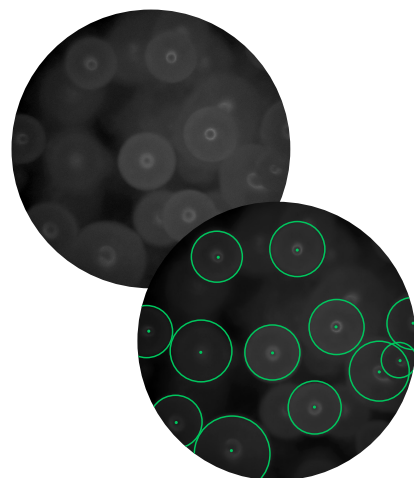
Photo-optical techniques are able to identify different kinds of particles according to their optical properties. A multi-object analysis and classification thus becomes possible.

### Visualization:

Detect single particles as well as agglomerates.

### Quantification:

The SOPAT software combines the visual information with quantitative results from automated image analysis.



## DATA ACQUISITION

### Data Treatment:

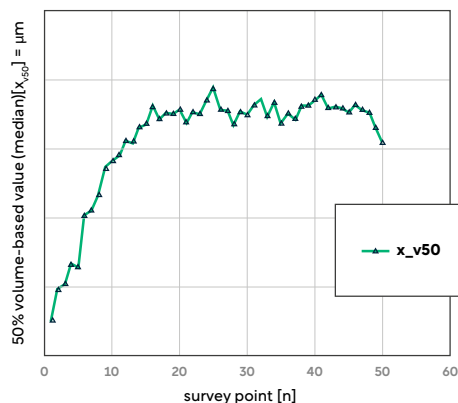
Starting from the original image, different steps of pre-filtering and background subtraction bring out the individual particles.

### Analysis:

The underlying algorithms can be used to differentiate particles according to their grey value, size and shape.

### An Example:

In the image below, a typical emulsion has been shown with the original image to the left and the analyzed image to the right. With SOPAT the user is able to obtain quantitative data as well as images.



## PROCESS CONTROL

### Interpretation:

Particle size distributions can be obtained inline by analyzing the images.

### Process Control:

SOPAT's combination of stroboscopic image acquisition and simultaneous analysis enables a continuous process control.

### Standardized:

SOPAT's automated image analysis detects particles and quantifies size and shape according to ISO standards: ISO 13322-1-2014, ISO 12322-2-2006.



# Anti-Fouling: Cleaning Without Process Interruption

## THE PROBLEM

Fouling and deposits are a challenge for all inline probes. The performance of optical measuring instruments can be particularly affected by contamination.

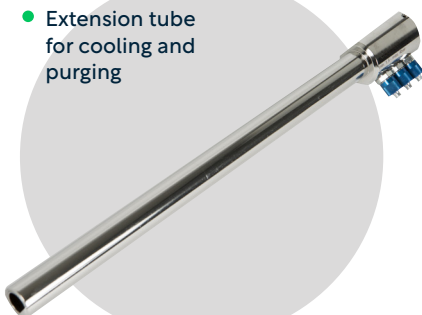
In the worst case, the measurement has to be interrupted and suspended until the next cleaning, causing a considerable loss of time and high costs. SOPAT offers its customers two solutions to these challenges:

## SOPAT ANTI-FOULING SOLUTION

This add-on is currently available for the Ma, Pl, Sc, and Pa inline probes. Deposits are removed by a tangentially directed fluid jet. This purging process can be used with either gases or liquids at a maximum pressure of 14 bar.

In addition, the built-in circulation of a cooling medium allows the temperature range for the inline probes to be extended from 120°C to 450°C.

- Extension tube for cooling and purging



## RETRACTABLE FITTINGS PROVIDED BY KNICK

Our partner Knick offers a fully automatic cleaning tool with its retractable fitting Ceramat WA155. The WA155 can be equipped with 12mm probes in 320mm length and thus enables their automated cleaning even in corrosive, high-temperature, toxic or pressurized process media.

- KNICK CERAMAT WA155



## CERAMAT HIGHLIGHTS

- Unique ceramic seal
- Possibility of cleaning the probe outside of the process
- Sensor switching without process interruption
- Can be combined with the 320 mm SOPAT probes with 12 mm diameter (Ma, Pl, Sc, Pa)
- ATEX version available.

# Technical specifications

SOPAT offers several probes covering a wide range of particle sizes, from 0.5 µm – 50,000 µm. Probes significant to pharmaceutical applications have been displayed below. The inline photo-optical method of measurement delivers real-time feedback from your processes.

Each system is made to fit the needs of the customer. With added flexibility for the hardware with various process connectors, probe length, material of construction, illumination modes as well as the SOPAT software with a vast library of image analysis workflows, SOPAT aims to deliver unique solutions to application specific problems.

Product Category	Microscopic	Mesoscopic		
Product Model	MM-2	VI Ma	VI Pl	VI Sc
Measurement Range [µm]	0.5 – 75	1.5 – 250	2 – 300	9 – 1,100
Field of View (diag.) [mm]	0.17	0.58	0.71	2.6
Tube Length [mm]	734	220 - 2,000		
Tube Diameter [mm]	76	12		
Pressure Range [bar]	0.5 – 3	0.01 – 320		
Process Temperature [°C]	0 – 200	-10 – 450		
Ambient Temperature [°C]	0-40			
pH-Level	0-14			
Probe Window Material	Quartz	Sapphire		
Probe Housing Material	1.4404 (316L)			
Probe Tube Material	1.4404 (316L)***			
Weight (w/o cable) [kg]	8	4.5		
Focus	Manual	Electronic		
Frame Rate [Hz]	15			
Image Resolution [MP]	5			
Power Input [VA]	141 (50-60 Hz)			
Certifications	CE, CIP/SIP, IP65	CE, CIP/SIP, IP65/IP68, ATEX		

\*On request, the following materials are also available: 1.4571(316Ti), 2.4402(C22 Hastelloy), 3.7165 (Titanium)



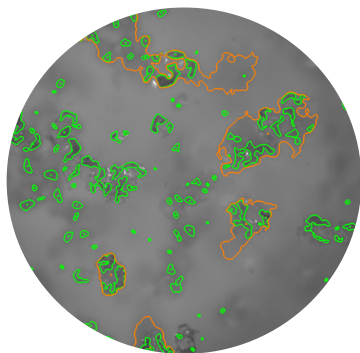
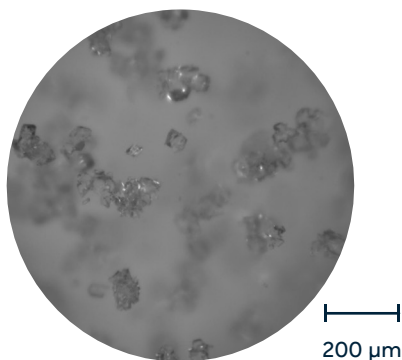
- ✓ NO DILUTION
- ✓ NO SAMPLING
- ✓ NO DELAY BETWEEN PROCESS AND ANALYSIS
- ✓ NO HUMAN FACTORS INVOLVED



# SOPAT in Pharma

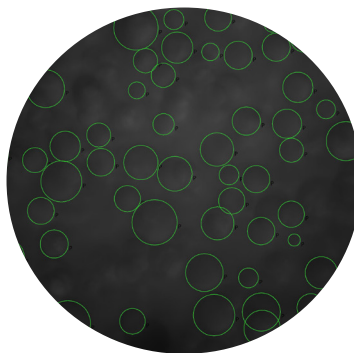
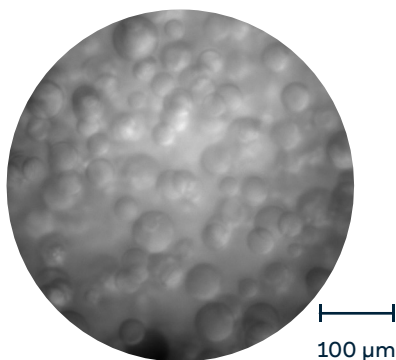
## Study characteristics of crystallization processes in API manufacturing

Monitor your crystallization processes from seeding to crystal growth. Critical quality attributes like size and morphology distribution, particle growth kinetics can be tracked in real-time significantly improving control over your process and subsequently the yield. Distinguish between single crystals and poly-twinned or aggregate crystals in your process using the filter options available within the SOPAT software.



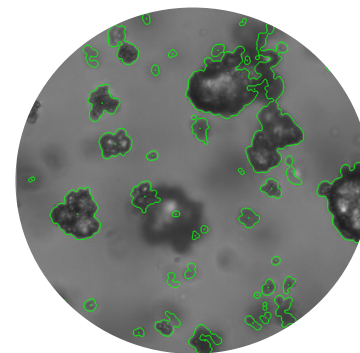
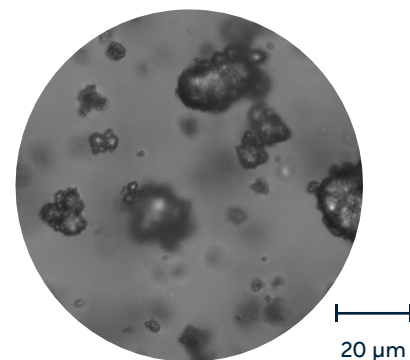
## Track transient behavior of microspheres and emulsions used in novel drug delivery systems

Achieving the correct size distribution in emulsions and microspheres used in complex injectables or drug delivery systems is paramount for drug administration as a broad distribution can render a particle fraction therapeutically useless while adding to compliance burden. Inline analysis with SOPAT helps avoid expensive off-specification batches and saves time which might be otherwise spent in sampling and offline analysis.



## Monitor pharmaceutical suspensions across size-reduction processes

Install the SOPAT probe at the outlet of size reduction equipment like mills or homogenizers. Monitor the particles size and morphology across multiple passes to optimize process time while making considerable savings in utility costs for energy intensive unit operations. With different modes of illumination, the SOPAT systems work well with dense suspensions.



# We welcome Parsum laser-based technology to our portfolio





We are pleased to introduce you to Parsum; a wholly owned subsidiary of SOPAT GmbH. Parsum specializes in the field of particle measurement technology for powder, granules, pellets and other solid phase systems.

With the Parsum patented fiber-optic spatial filter technique for particle measurement, it becomes possible to analyze several thousand particles per second.



The Parsum probe's ability to disperse the particle flow in the process vessel sets it apart from other in-line measurement systems. Through in-line dispersion it is feasible to reliably determine the particle size in moist or sticky materials in a manner comparable to laboratory techniques.

Product Model	IPP 80-P
Particle size measurement range (µm)	50 - 6,000
Particle velocity measurement range (m/s)	0.01 - 50
Measuring rate (particles/s)	up to 20,000
Process temperature (°C)	-20 to +100
Process pressure (bar)	<4
Material, in contact with product:	stainless steel (L316), sapphire, epoxy resin
Probe tube dimensions (length/diameter) (mm)	280×25 (optionally 380×25)
Electronics-housing dimensions (diameter/depth) (mm)	90 x 60
Electronics-housing temperature (°C)	-10 - 60
Housing protection class	IP65
Light source	Laser (laser class 1)
Power consumption (W)	2
Interfaces	Particle distributions and attributes as an ASCII file (Excel compatible), optional: 4–20 mA, TCP/IP, OPC
ATEX certificate	IBExU14ATEX1247
Probe identification 	II 1/2G Ex ia op is IIB T4 Ga/Gb II 1/2D Ex ia op is IIIC T125°C Da/Db
Barrier-box identification 	II (1)G [Ex ia Ga] IIB II (1)D [Ex ia Da] IIIC



# Introducing Parsum

## Monitor fluidized bed granulation for batch-to-batch consistency

With Parsum, the user is able to quantify the effects of process parameters on trends in the granulation process as well as monitor any defects like blocked nozzles or break down of the fluidized bed in real-time.



## Continually determine the layer thickness and agglomerate fraction of pellet coating in fluidized bed

The spray rate in pellet coating processes is a crucial parameter that affects the coating layer thickness. With the Parsum IPP 80-P, the spray rate can be increased in a controlled manner while continuously monitoring the particle size distribution avoiding agglomeration and improving batch-to-batch consistency.



## Track the granulation end-point in high-shear mixing and pelletization

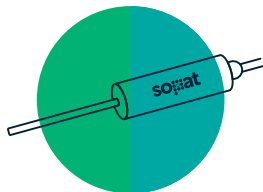
Through inline dispersion, the IPP 80-P probe can handle dry as well as wet mixing and granulation processes.



**parsum®**  
A SOPAT brand

# Integration into production line

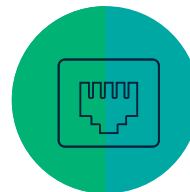
- Applies to **SOPAT**
- Applies to **Parsum**



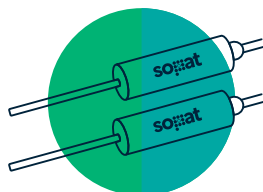
**Flexibility** with probe lengths, materials of construction, and process connectors enables a comfortable integration into your existing process.



**Modular design** of the individual components (probe, housing, computer) allows an easy handling.



**Easy connection** to your process control system (PCS) via Modbus TCP/IP, OPC UA or others is given.



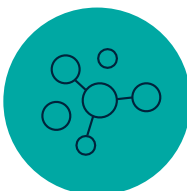
**Connect multiple probes** for simultaneous monitoring of various processes.



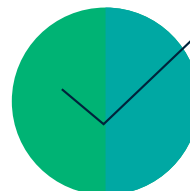
**Successful correlation** with traditional benchtop measurement techniques



**Automated cleaning** with KNICK Ceramat for high fouling systems



**Inline disperser** for reliable measurements in moist and sticky systems



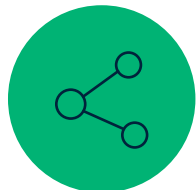
**Certifications:**  
ATEX, 21 CFR  
GMP compliant



# 5 Steps to Your Own Inline Particle Measurement System



**Define your problem and your process/application with the help of our checklist.**



**Get to know the system:**

- a) On-site measurements.
- b) In-house laboratory measurements of small samples.



**Monitor your process thanks to an optimal inline measurement system tailored to your needs.**



**Profit from all the different ways to test the system:**

- a) Measurement as a Service
- b) Renting
- c) Try and Buy
- d) Direct Purchase.



**Take advantage of our knowledge.**

We support you during the installation of our system and also offer comprehensive support during system operation.



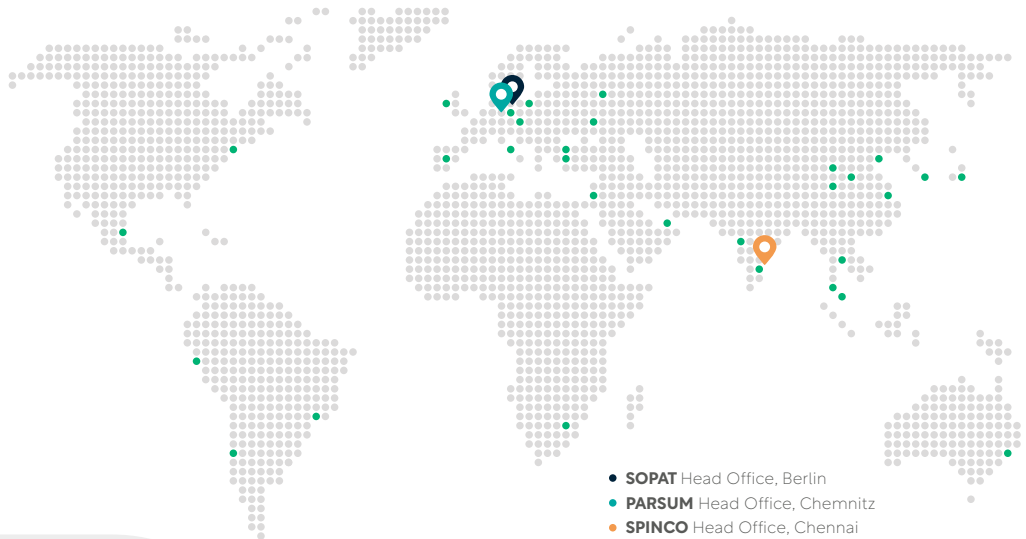
# R & D An Essential Part of Our Company's Philosophy

New approaches are constantly being tested to improve the **SOPAT** system. We maintain many cooperations with universities and are active in many research projects. In addition, we support the next generation of young scientists.

**SOPAT** sees itself as a research partner, system supplier and employer for young people and maintains a close relationship with a number of international research institutes. **SOPAT** is proud to work with the new generation of emerging scientists.



# Globally Active Thanks to a Strong Sales Network



- **SOPAT** Head Office, Berlin
- **PARSUM** Head Office, Chemnitz
- **SPINCO** Head Office, Chennai

## SOPAT GmbH

Bergholzstraße 8 | 12099 Berlin | Germany  
+49-30-398-2020-00

[info@sopat.de](mailto:info@sopat.de) [sopat.de](https://www.sopat.de)

## Parsum GmbH

Reichenhainerstraße 34-36 | 09126 Chemnitz | Germany  
+49-37-126-7586-90

[info@parsum.de](mailto:info@parsum.de) [parsum.de](https://www.parsum.de)



**parsum**<sup>®</sup>  
A SOPAT brand

**sopat**  
Make every detail count