# Particle ID – Analysis Service

Micro Particle Isolation, Counting and Identification

Simple Cause Analysis

Your Partner for Foreign Particle Studies, Method Development and Validation

rapID

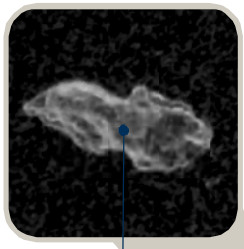
# Analysis Service for **Foreign Particles**

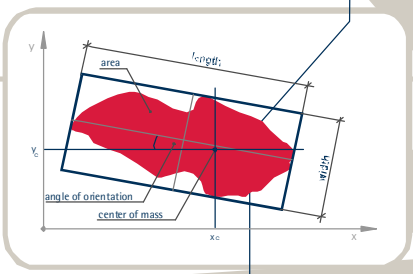
## How You Benefit from the Particle Specialists:

In using our particle laboratories, you gain access to our long years of experience and ISO 9001:2000 documented quality in the development of methods and routine analyses for the isolation, detection and identification of disturbing particle contamination.

In our laboratories we use particle image analyse and combined Raman identification customized for foreign particle analysis, as well as specifically selected extension modules and additional methods, to detect contamination in production processes worldwide.

rap.ID provides you with information about the number, size and chemical composition of the particles. The statistically relevant particle identification allows you to find and quickly eliminate contamination sources.



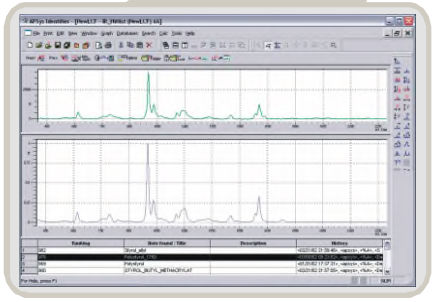



13 µm Polystyrene

**This is how you use the rap.ID Particle Analysis Service:**

- You send us the product to be analyzed.
- We contact you to inquire about the scope of the analysis and develop a measurement method.
- Within a very short time you receive the result of the analysis, a clear and concise protocol, microscope images of the particles and a final examination report, all produced by our experts.

| Substance | 10-25 µm | 25-50 µm | 50-100 µm |
|---|---|---|---|
| Rubber | 2 | 1 | 0 |
| Paper | 5 | 2 | 1 |
| Polyethylene | 28 | 7 | 2 |
| Metal | 14 | 2 | 0 |
| **Identified** | **229** | **12** | **3** |
| **Counted** | **2675** | **825** | **23** |



## Particle Identification Technology from rap.ID:

We use our patented filtr.AID particle isolation and identification technology to detect single particles and assign them to their exact source of contamination on the basis of their respective chemical structure. Our filtr.AID technology enables us to isolate particles from a vast range of different products through vacuum filtration on the filtr.AID membrane. The Particle Finder then automatically analyzes the filter membrane according to predetermined specifications and determines the distribution of particle sizes. The cleaning quality of the used materials and solvents is documented in a blind test. Our Particle Explorers use automated Raman spectroscopy for the reliable determination of the size, shape, and chemical composition of particles 500 nm and larger.

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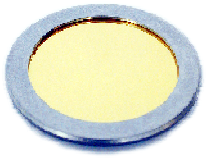
# rap.ID Particle Identification Technology

## Particle Isolation:

The filtr.AID membrane allows the isolation of particles from any medium. We choose the nuclear pore size and the size of the effective filtration area according to the respective measuring task during method development. Documented blind samples are the first step in ensuring workspace, media and equipment cleanliness.



## Particle Recognition:

The fully-automated image analysis allows the evaluation of the entire particle loaden area of a sample and the determination of particle size distribution. In addition, shape parameters such as roundness and rec-tangularity, are also evaluated.

| Size class | > 10 µm | > 25 µm | > 50 µm | > 100 µm |
|---|---|---|---|---|
| Number | 1850 | 173 | 52 | 1 |

## Particle Identification:

The Particle Explorer automatically selects the particle on the basis of certain predetermined criteria and positions it into a laser focus of approx. 2 µm. It is also possible to manually select irregular individual particles found during optical inspection. Although integration time and other parameters are usually selected automatically, they can be adjusted manually as well.

The integrated spectrum analysis removes the fluorescent background, and the database search automatically analyzes the position and area below the peaks, finding the best match from the substance database.

The rap.ID database contains almost all the materials that are relevant in cleanroom production, including lubricants, rubber tubes and seals, clothing, human dust, organic and inorganic filling materials, rubber stoppers, packing materials as well as wiper/cleaning agents and cloths.

Your specific auxiliary and active substances can be easily and reliably integrated into your customer database.

Polystyrene, Rank: 952

## Method Development and Validation:

We assist you in the preparation of foreign particle studies for pharmaceutical development, which includes every process from method development to routine testing for foreign particles. Method validation uses performance parameters which are decisive for the value of the analysis, such as linearity, robustness, reproducibility, and precision. We draw our method validation experience from several successful validation studies, specifically in the foreign particle analysis of modern dry powder inhalers and nasal spray products.

## Documentation und Compliance:

Quality management compliant to the internationally recognized DIN EN 9001:2000 standards is the key requirement for the production of our particle analysis equipment, as well as for our analyses and every other process in the company. The measuring instruments in our laboratory have to pass the qualification process as well, and are only used after successful performance verification. They are also subject to continuous measuring instrument control.

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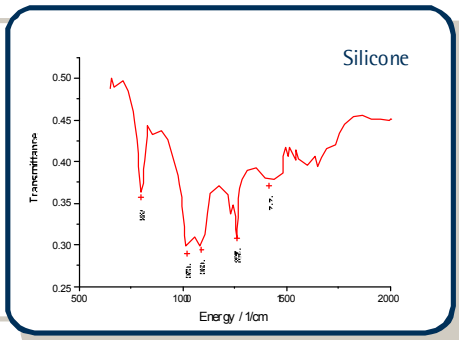
# Other Particle Measurement and Identification Methods

## Chemical Composition:

Our default database, in combination with automated Raman spectroscopy, enables us to identify about 90% of all organic and inorganic materials. EDS spectroscopy, a complementary method, is only required to distinguish metals and alloys which cannot be detected through Raman. The combined power of both techniques allows us to identify almost any contaminant particle larger than 500 nm.

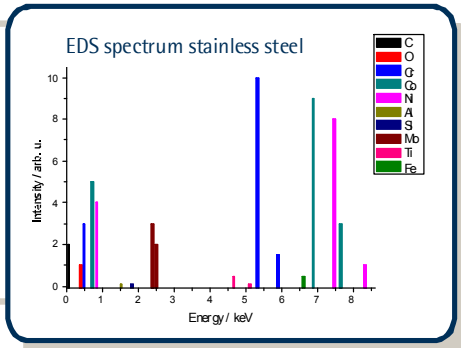
## FT-IR Microspectrometry:

Our FTIR microscope allows the easy identification of particles larger than 70 µm.
FTIR spectroscopy yields vibration spectra which allow access to the extensive IR databases, identifying the source of thousands of small particles with previously unknown Raman spectra with the help of the spectrum of one larger particle.




## Illustration/Element Analysis with REM/EDS:

REM/EDS provides the elemental distribution of a sample with a lateral resolution of approx. 500 nm and is therefore used as a complementary method to our Raman spectroscopy.




## Particle Size Distribution with Light Scattering:

We can offer the measurement of (subvisible) particles from parenterals in compliance with USP <788> as a routine analysis. You can then use the result of the optical particle counting to quickly obtain information about the particle contamination of the sample. In addition, we develop methods for you for foreign particle counting using optical particle counters (OPC).

| | > 10 µm | > 25 µm |
|---|---|---|
| sample 1 | 250 | 15 |
| sample 2 | 475 | 23 |

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