

# Particle Source in Respiratory Drugs



## Foreign Particle Studies and Routine Investigations:

Particles within a size range of between 2-15  $\mu\text{m}$  play a particularly significant role in the production of inhalative drugs. Since these particles are not excreted after inhalation but remain in the alveolar tissue, the inhalant

manufacturers as well as the regulatory authorities attach great importance to the identification of foreign particles of this size.

### Research:

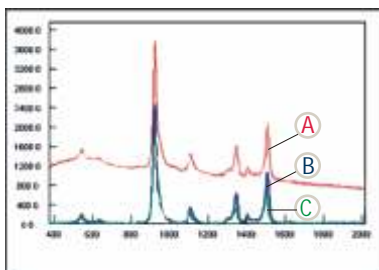
Studies show that more than 95% of the foreign particles of this substance class are of organic origin and can therefore not be assigned to any substance using REM/EDS analysis. However, thanks to our years of unique experience with our Particle Explorers we are able to perform automated high-throughput particle identification.

- Foreign particle studies in the Dry Powder Inhaler formulation
- Foreign particle status of active and auxiliary agents
- Method development and validation of foreign particle studies
- Routine foreign particle monitoring in a nasal spray suspension
- Particle emission behavior testing of capsules and inhaler parts



## Results: Dry Powder Inhaler

The study, accomplished in cooperation with a leading manufacturer of dry powder inhalers, shows that after successful method development a specific foreign particle profile can be easily provided.



(A) original (B) background corrected (C) database match

### Comparative Investigation

Substance	First Batch			Second Batch				
	No.	>2 $\mu\text{m}$	>10 $\mu\text{m}$	>25 $\mu\text{m}$	No.	>2 $\mu\text{m}$	>10 $\mu\text{m}$	>25 $\mu\text{m}$
Titan dioxide	4	4	0	0	3	3	0	0
Polystyrene	2	2	0	0	ND	ND	ND	ND
Polypropylene	2	1	1	0	ND	ND	ND	ND
<b>Polyvinylacetal</b>	<b>ND</b>	<b>ND</b>	<b>ND</b>	<b>ND</b>	<b>24</b>	<b>20</b>	<b>4</b>	<b>0</b>
Carbon	12	11	1	0	7	6	0	1
LC Hydrocarbon	59	38	19	2	ND	ND	ND	ND
Calcium Carbonate	ND	ND	ND	ND	2	1	1	0
Carbohydrate	ND	ND	ND	ND	4	0	4	0
Protein	ND	ND	ND	ND	7	0	4	3
Fluorescence	10	7	3	0	16	11	4	1
Unidentified	4	0	2	2	7	6	0	1
Sum of particles	93	63	26	4	70	47	17	6

Comparison of foreign particle data from two batches of dry powder inhaler components, determined using the Liquid Particle Explorer (ND = not detected)