Liquid Particle Explorer® Application Note

Identification of Particulate Matter - Reject Small Volume Parenteral

Sample Description

rap.ID test sample: Small volume parenteral (SVP) rejects in a (50 ml) solution which included white particles and fibers.

Purpose of Analysis

Parenterals are subject to high requirements in regards to purity. These parenteral solutions are regulated by the national pharmacopoeias and must be free of any visible particles (particle of 50 µm or more.) Serious efforts in production and quality assurance are required in order to ensure top quality and compliance.

Therefore, a 100% inspection of all parenterals is required. If contamination occurs it is possible through particle ID to identify and eliminate the particle source during processing.

Procedure

A product's primary package is opened and its contents are sucked through a patented membrane filter with an area of 4 mm in diameter.

The particle-loaded area is then automatically analyzed with the Liquid Particle Explorer®. Each particle larger than 50 µm is identified by the system. The following parameters are used:

- Exposure time per particle: 40 s
- Automated picture analysis of 100 Fields (500 µm x 500 µm)
- Minimum particle length >50 µm

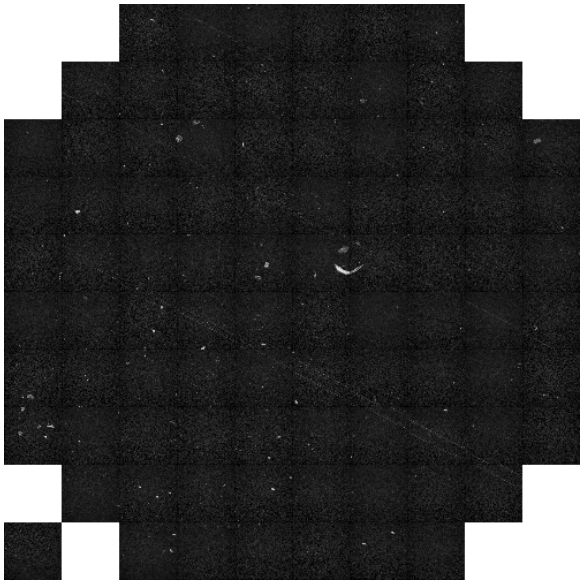

Figure 1: 89 automated generated scan fields.

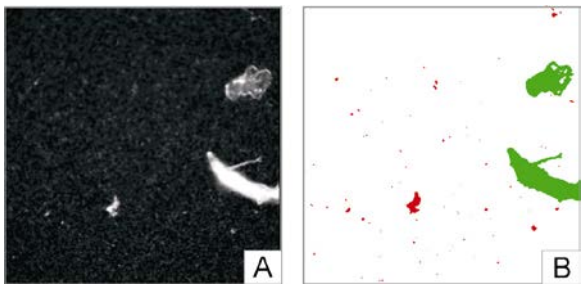

Figure 2:
A dark field picture of one field 500 µm x 500 µm
B picture analyses of A. Measured particles are marked in green, all other particles in red.

Results Summary

Substance	Number	Size	
-	-	>=50	>=100
Cellulose	4	4	0
Polyethylene	4	2	2
Total	**8**	**6**	**2**

Table 1: Identified Particle > 50 µm from the 50 ml SVP solution.

Each of the identified particles gave a recognizable spectra that was identified by the APSys - Identifier® database. The main product contamination was identified as a polyethylene fiber. This large fiber was seen in the visual inspection and was the source of contamination and the cause for rejection. Some smaller PE particles were found as well. Four other smaller cellulose particles did not cause the actual reject, but these findings show that a cellulose source could cause trouble in the future.

Benefits

Foreign particles identification of the SVP reject solution pointed directly to the source. It is also possible to verify this result from sampled material identification located in production/filling lines. The user can add samples from the production process to the database within minutes. APSys – Identifier® software allows the particle spectra to be easily compared with these samples, new databases can be generated for different products, materials or filling lines.

Examinations performed with the Liquid Particle Explorer® allow for statistically relevant and comparable conclusions about the chemical composition of the particles in a short time period. The main contamination sources can be detected by the particle spectrum of a product sample. Polyethylene was identified as the source and the cause of malfunction of the filling process was identified. It took three people 4 hours to remove the source of contamination from the rejected product..

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