

ISO8871-3 quantifies contamination on elastomers

The ISO 8871-3 is widely used to detect fibers and other kind of particulate contamination on rubber stoppers and other elastomers used in pharmaceutical manufacturing. The level of contamination found on the stopper has a direct bearing on the reject levels of parenterals produced utilizing such stoppers.

Enumeration and Size Detection of Particles with the Single Particle Explorer

10 rubber stoppers were immersed in 100 ml 0.1 % Tween solution and shaken for 10 minutes. This solution was filtered through a 0.8 µm gold coated polycarbonate membrane (filtr.AID) on an effective filtration area (EFA) Ø 10 mm. Before and after analysis, a blank control was performed to ensure system cleanliness.

This membrane was evaluated by means of the qualified automated counting system, Single Particle Explorer (SPE) CSS, rap.ID Particle Systems.

Results from the automated imaging analysis

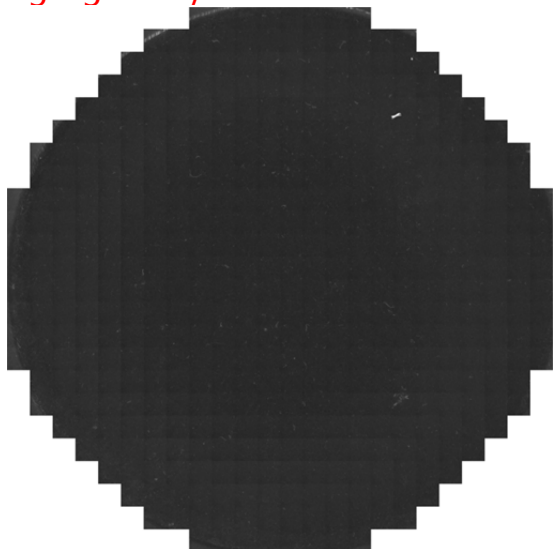


Fig. 1 An image montage of the scan of the entire EFA Ø 10 mm (568 fields of view).

Integrated dark-field and imaging analysis is able to size and count 5 micrometer particles with a resolution of 5 Pixel/Particle. The shape/morphology of the particle is analyzed as well.

The SPE was set up to measure an EFA diameter of Ø 10 mm. Measurement time was 15 minutes.

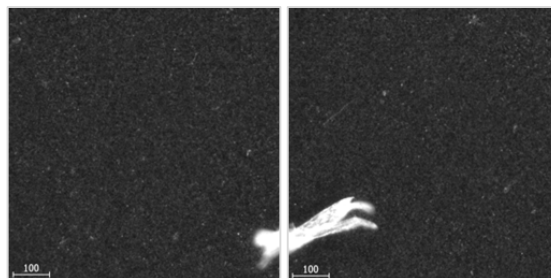


Fig. 2 Two fields of view exhibiting the largest fiber (428.1 µm)

The report was produced in compliance with 21 CFR Part 11.

Table 1: Analysis result: Particle count per 10 stoppers

Distribution [µm]				
10-25	25-50	50-100	100-250	≥ 250
2009	123	32	8	1

Conclusion

The test procedure and the compliant report according to the ISO 8871-3 successfully document the contamination level of rubber stoppers. This analysis provides the pharmaceutical manufacturer with valuable information regarding primary packaging material cleanliness.

Fibers were recognized and characterized by high power magnification microscopy. Fibers overlapping individual images were successfully stitched. Their morphology is recognized automatically.

Further identification steps (micro-spectroscopy) can be performed with the same instrument directly on the filter surface.