



Ebatco Nano

A Bimonthly Newsletter

Nano

Brief

Exhibitions

We will be participating in our final tradeshow of 2026.

- October 28-29 – MD&M Midwest 2026, Booth #3636, Minneapolis Convention Center, Minneapolis, MN

Visit our booth to talk with our staff scientists about medical material testing, characterization, and failure analysis that can strengthen your R&D, QA and regulatory compliance efforts. See you soon!

At this show, Ebatco President, Dr. Dehua Yang, FASM, will be presenting a session on: **Nanoscopic Characterization of Medical Materials and Devices**. In this presentation, an introduction and overview of several advanced characterization techniques at nano scale – available, but yet to be broadly employed – will be provided. Experimental results and analyses obtained on different kinds of medical material and device specimens using various techniques including nanoindentation, nanoscratch, atomic force microscopy, and nanoliter contact angle measurements will be used to highlight the advantages and benefits of the techniques for enhanced characterization of medical materials and devices at nanoscale. More information on this event can be viewed at <https://mpd.4spe.org/event/minitec-conference-at-mdm-midwest-october-28-2026/>.

Ebatco

Ebatco continues to grow, and we're thrilled to welcome a talented new professional to our team. As we expand our expertise and service offerings, we're excited about the

experience and fresh perspective they bring. Please join us in welcoming:

Clare Yoerger, Nano Analytical and Testing Lab Technician

Ms. Clare Yoerger graduated from the University of Wisconsin - La Crosse in 2026 with a B.S. in Chemistry and Spanish. Her undergraduate research focused on using an iron-based phthalocyanine catalyst to optimize organic oxidations in environmentally friendly ways. During her time at La Crosse, she studied instrumental analysis in addition to using GCMS for research. Clare lived in Chile and Spain for several months, participating in full immersion of the language and cultures. She is excited to join Ebatco as a NAT Lab Technician, bringing both her analytical and cultural experiences, to better serve customer needs.

Case

Study

Comparing the Light Obscuration and Microscopy Methods in USP Ch. 788 & 789

Large particles entering the bloodstream can cause blood vessel blockages, localized inflammation, and unintended immune responses, while particles in the eye can cause irritation, inflammation, and vision impairment. The United States Pharmacopeia (USP) Chapter 788 provides two methods for testing particulate sizes in parenteral solutions. Chapter 789 provides nearly identical methods for testing ophthalmic solutions. The testing methods applicable to both Chapters 788 and 789 are crucial to help promote the health and safety of the product's users, and a comparison of these methods allows for a better understanding of the advantages for each. The first method is the light obscuration test, a technique in which a liquid is drawn through a light beam. Particles in the liquid obscure the light, resulting in intensity drops which can be counted and used to calculate each particle's size. The second method is by the microscopic particle count test, a technique in which a liquid is drawn through a fine filter, and particles left behind on the filter are counted manually using a microscope. The particles are sized with a USP circular diameter graticule, which has references of 10 μm and 25 μm . The two methods are intended to complement each other. The light obscuration method is automatic, fast, and accurate. When a solution has

reduced clarity or increased viscosity, light obscuration testing becomes less reliable and microscopic particle count testing is more effective.

Ebatco’s NAT Lab has the capability to perform both light obscuration testing, with a Beckman Coulter HIAC 9703+ Particle Counter, and microscopic particle count testing, with a Fein Optic Microscope. Two samples, one for each chapter, that were applicable to both methods in their respective chapter were tested. For USP Chapter 788, a 100 mL 0.9% saline parenteral solution from a sterile IV bag was tested, and for USP Chapter 789, 100mL of eyewash solution was tested. The data reported in Table 1 shows the results of both the light obscuration tests and the microscopic particle count tests. All test results were well below the limits described in USP Chapters 788 and 789. The methods produced results that were similar to each other, demonstrating the interchangeability of the methods. Figure 1 shows two eyewash particles larger than 10 μm and smaller than 25 μm .

Sample	Table 1 Particle Count Results for Light Obscuration and Microscopy					
	Method 1: Light Obscuration			Method 2: Microscopy		
	#/mL ($>10\ \mu\text{m}$)	#/mL ($>25\ \mu\text{m}$)	PASS/FAIL	#/mL ($>10\ \mu\text{m}$)	#/mL ($>25\ \mu\text{m}$)	PASS/FAIL
IV Bag	2.88	0.05	PASS (788)	1.62	0.08	PASS (788)
Eyewash	0.42	0.05	PASS (789)	0.52	0.04	PASS (789)

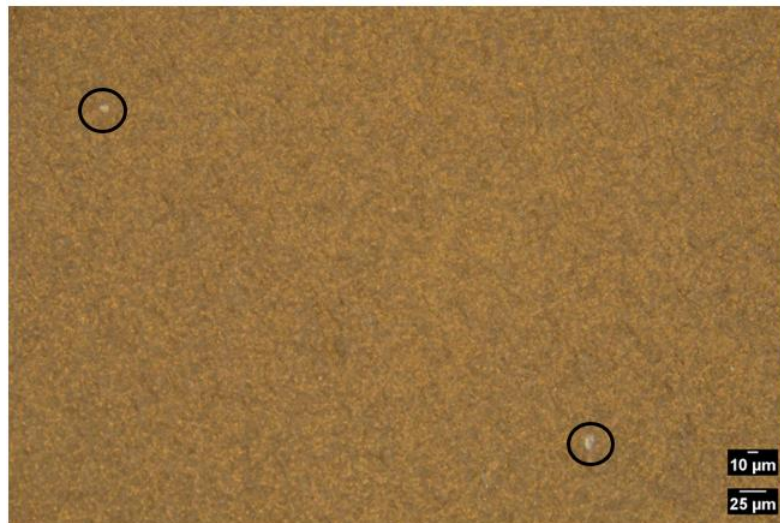


Figure 1. Microscope image of two particles larger than 10 μm and smaller than 25 μm found in the eyewash solution on a filter. The particles have been circled in black.

The particle counting tests showed that both methods report similar values for both the parenteral and the ophthalmic solution. The light obscuration method in USP 788 requires that there be less than 25 particles greater than 10 μm in diameter

and less than 3 particles greater than 25 µm in diameter per milliliter of solution. The microscopic particle count method in USP 788 requires that there be less than 12 particles greater than 10 µm in diameter and less than 2 greater than 25 µm in diameter per milliliter. Both the light obscuration method and the microscopic particle count method in USP 789 require that there be less than 50 particles greater than 10 µm in diameter and less than 5 greater than 25 µm in diameter per milliliter. The microscopic particle count method additionally requires that there be less than 2 particles greater than 50 µm per milliliter. There were no particles greater than 50 µm detected in the eyewash sample.

Each sample passed the respective USP chapter, and each method detected a similar particle count. The similarity between the two methods illustrates the advantages of both methods being included in the standards, as their interchangeable nature allows for a wide range of products to be tested. USP chapters 787, 788, and 789 regulate particle counts in parenteral and ophthalmic solutions to ensure the health and safety of patients who use them.

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