INTERLABOR
BELP AG

April 2026

ANALYTICS

Quantification of Particulate Contamination in Liquids

Introduction

The determination of particulate contamination in medicinal products, particularly injectable preparations, is mandatory in accordance with the regulatory requirements of the relevant pharmacopoeias (e.g., Ph. Eur. 2.9.19 and USP <788>).

For the testing of injectable solutions, the pharmacopoeias describe two established methods:

- Method 1: Light Obscuration Test (automated)
- Method 2: Light Microscopy (visual)

With the acquisition of the LS-20 particle counting system from Lighthouse Instruments, Interlabor Belp AG strengthens its analytical service offering. The laboratory now provides both Method 1 (automated light obscuration testing), particularly for clear injectable solutions, as well as Method 2 using light microscopy.

Principle of the Light Obscuration Method

The light obscuration method is based on the optical detection of particles in a liquid. A defined sample volume is passed through a measurement cell where a laser beam is directed at a photodetector. When a particle passes through the light path, it briefly blocks the light. This signal change is electronically recorded and evaluated to determine particle count and particle size.

Areas of Application

- Testing for particles in parenteral solutions (injectable and infusion products)
- Quality control of biopharmaceutical products (e.g., proteins, antibodies)
- Control of dialysis and rinsing solutions
- Testing of ophthalmic products (e.g., eye drops)
- Determination of particulate contamination in primary packaging materials (e.g., elastomers, containers) in accordance with ISO 8871-3

Our System: LS-20 Particle Counter

For light obscuration testing, we use the LS-20 particle counting system from Lighthouse Instruments. Specifically developed for the pharmaceutical industry, the instrument enables precise quantification of particles in the size range from 2 to 50 micrometers.

It complies with the requirements of the relevant pharmacopoeias (Ph. Eur. 2.9.19, USP <788>, JP 6.07). Particles are detected and classified in the following size thresholds: 2.0, 5.0, 7.0, 10.0, 15.0, 25.0 and 50.0 µm.

Requirements for the Sample Material

- The sample must be optically clear, as opaque solutions (e.g. emulsions or suspensions) may lead to measurement errors or detector saturation. In such cases, microscopy is recommended.
- Samples must be provided in clean, particle-free containers. The container material must not release particles.
- For standard analyses according to the pharmacopoeia, a minimum sample volume of 25 mL is generally required. Smaller volumes are possible (e.g. according to USP <787>), but require methodological adaptations.
- Products with a viscosity greater than 10 mPa·s are not suitable for light obscuration testing; in such cases, microscopy is preferred.
- For unknown sample matrices, a suitability test is required to exclude potential matrix interferences and, if necessary, to adapt the method.

Microscopy vs. Light Obscuration

Both methods have specific strengths and limitations. The selection depends on the product type, matrix characteristics, and the analytical objective. Table 1 provides an overview of the key features of both methods.

Key Facts – Particle analysis at Interlabor Belp AG

As an independent GMP-compliant testing laboratory, Interlabor Belp AG supports pharmaceutical and biotechnology companies in the regulatory-compliant determination of particulate contamination.

- Analytical quality: GMP-compliant testing available
- Sample volume: 25 mL (smaller volumes available upon request)
- Turnaround time: Standard: 10 working days or
Express: 5 working days
- Price: on request

Conclusion

Light obscuration testing and light microscopy are two well-established methods recognized by the pharmacopoeias for the quantification of particulate contamination in parenteral solutions. Both approaches ensure regulatory compliance and are selected according to product specifications and matrix characteristics.

Light obscuration testing is characterized by high reproducibility, automated execution, and efficient analysis times, making it the preferred method for routine testing of clear, aqueous injectable and infusion solutions.

Microscopy offers advantages when light obscuration testing is not applicable, for example in viscous or opaque solutions. In addition, it enables morphological analysis and partial identification of particles (e.g. glass fragments, fibres, rubber abrasion), which can be particularly valuable in root cause investigations of contamination.

Figure 1: LS-20 Particle Counting System from Lighthouse Instruments

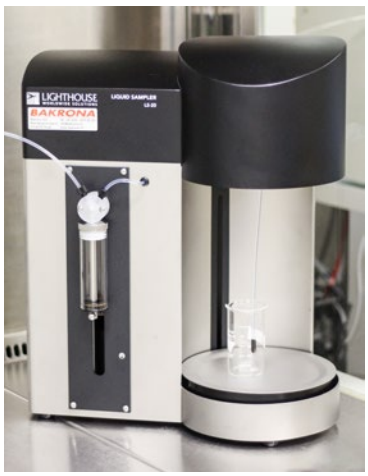

Table 1: Microscopy vs. Light Obscuration

Criterion	Light Obscuration	Microscopy
Principle	Detection of light blockage by particles in a liquid stream	Visual observation and counting under a microscope
Particle size range	2–50 µm	approx. 2–500 µm
Quantification	Automated	Visual, subjective
Identification	Counting only, no particle identification	Morphological identification and partial indication of particle origin
Analysis time	Fast, a few minutes	Time-consuming (sample preparation and counting)
Application	Only suitable for clear solutions	Suitable for viscous, opaque, or turbid solutions
Reproducibility	High	Dependent on operator experience and attention
Standards	Both methods are referenced in pharmacopoeias and ISO standards	

References

[1] *Ph. Eur. Chapter 01/2021:20919: Particulate contamination: Sub-visible particles*

[2] *USP-NF 05/2021 <787>: Subvisible Particulate Matter in Therapeutic Protein Injections*

[3] *USP-NF 05/2013 <788>: Particulate Matter in Injections*

[4] *USP-NF 05/2024 <789>: Particulate Matter in Ophthalmic Solutions*

[5] *JP XVIII 6.07 : Insoluble Particulate Matter Test for Injections*

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