Particulate Matter Test

Particulate matter in injections and parenteral infusions consists of mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions. Measuring the number of contaminating particles is very important for patient safety, because particles in injections and parenteral infusions may be harmful. Such as, if there are too many particles, these particles may clog the capillaries of the blood system. Therefore, USP requires drug and biopharmaceutical manufacturers to comply with their strict regulations on the number of particles present in the final drug when they perform injections and infusions. In addition, it is recommended to conduct liquid particle testing in a controlled environment to further reduce the risk of contamination during the test.

CD Formulation laboratory is cGMP-compliant and equipped with state of the art analytical instruments. We have experienced analysis experts who can work with our formulation and manufacturing team to provide you with particulate matter test services. Our particulate matter test is performed in accordance with pharmacopeia methods, in particular USP <788>. The accurate and robust data generated of particulate matter test, which can help you to make an appropriate risk assessment for your finished drug products.

Sources of Particulate Matter

- The solution itself and its ingredients
- The production process and its variables (e.g., environment, equipment, personnel)
- The product's packaging
- The preparation of the product for administration (e.g., manipulating the product, the environment in which it is prepared)

Our Methods of Particulate Matter Test

USP < 788 > provides two methods to detect these particles: method 1 - Light Obscuration is the preferred method, unless the product is unsuitable due to viscosity or transparency, method 2 - microscopic analysis is applied. For all other solutions, they are first tested by method 1, if a solution fails to meet prescribed limits it may then be tested by method 2.

The particles' average cumulative counts, average differential counts, average cumulative counts per ml and average differential counts per ml. The acceptance criteria are as follows:

Methods	Type	Diameter
Light obscuration	Parenteral Infusion or Injectable Solutions with a nominal content of >100 mL	≥ 10μm
		≥ 25μm
	Parenteral Infusion or Injectable Solutions with a nominal content of <100 mL	≥ 10μm
		≥ 25μm
	Ophthalmic Solutions	≥ 10μm
		≥ 25μm

		≥ 50μm
Microscopic assay	Parenteral Infusion or Injectable Solutions with a nominal content of >100 mL	≥ 10μm
		≥ 25μm
	Parenteral Infusion or Injectable Solutions with a nominal content of <100 mL	≥ 10μm
		≥ 25μm
	Ophthalmic Solutions	≥ 10μm
		≥ 25μm
		≥ 50μm

Deliverable

- Data analysis
- Provide full study report

References

1. Langille S E. Particulate Matter in Injectable Drug Products[J]. PDA J Pharm Sci Technol, 2013, 67(3): 186-200.
2. Perez M, Maiguy-Foinard A, Barthélémy C, et al. Particulate Matter in Injectable Drugs: Evaluation of Risks to Patients[J]. Pharmaceutical Technology in Hospital Pharmacy, 2016, 1(2): 91-103.