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Healthcare Companies.



Sub-Visible Particle Testing - Medistri

🚀 Sub-Visible Particle Testing

Measuring the number of contaminating particles is very important for patient safety, because particles in injections and parenteral infusions may be harmful. Medistri's laboratory performs medical device particulates testing on injections, parenteral infusions and medical devices as particulate matter is produced through various sources during processing. Particulate matter in injections and parenteral infusions consists of mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions. There is no single method for testing parenteral products or medical devices when conducting particulate analysis.

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.

When testing for particulate levels of a medical devices, Medistri considers the following:

- Manufacturing
- Sterilisation
- Shipping
- Distribution
- Packaging
- Shelf storage
- and use with other devices & materials

👉 According to USP <788> Injections, the Light Obscuration Method and the Microscopic Method are the preferred approaches to analyze particulate matter.

Sub-Visible Particle Testing Through Light Obscuration Method: This method analyses the device rinse solution or injectable product using a light obscuration particulate analyser.

Sub-Visible Particle Testing Through Microscopic Method: This method filters the device rinse solution or injectable product through a 0.8 µm grey gridded filter. The filter is then counted microscopically at 100x to determine the number of particles, counting particles in the entire test solution.

🌐 To learn more about our Ethylene Oxide Residual Analysis services visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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#Pharmaceutical #MedicalDevices #MedTech #BioTechnology
#SterilizationServices #Laboratory Services
#USP788 #particletesting #subvisibleparticle #parenteral
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<https://www.medistri.swiss/service/our-laboratory>