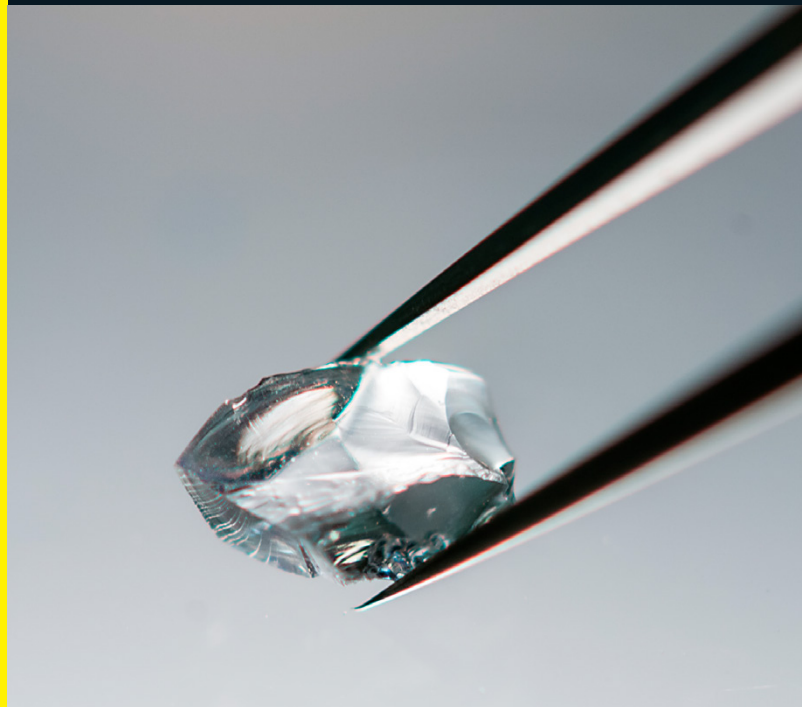


Particle Validation Standards

Custom manufactured defect kits designed to validate the visual inspection process for manual and automated processes



Benefits

- Support the reliable and efficient control of particulate contamination
- Broad line of custom-manufactured standards
- Designed to challenge and validate visual inspection methods
- Support training and testing of human inspectors
- Economical and convenient

Product Information

To help meet the challenges of detecting contamination via visual inspection, Sartorius offers a broad line of custom-manufactured standards designed to validate the visual inspection process used for Quality Assurance of pharmaceutical solutions. Particle Validation Standards (PVS) from Sartorius provide economical, convenient alternatives to the time-consuming, tedious task of preparing standards in-house, and they are effective training aids for manual inspection systems.

Quality Control For Parenteral Fluid Inspection

As the international demand for pharmaceutical product quality increases, so does the need for reliable, efficient control of particulate contamination.

Particulate contamination refers to the unintentional presence of extraneous, mobile and undissolved particles in a parenteral solution. These particles are of various size, but those detected by visual inspection are generally greater than 50 µm.

Several types of particulate contamination in parenteral fluids have been identified. These include such contaminants as glass, plastic, rubber, fibers, and metal, etc.

Particle Validation Standards include

- Glass spheres and shards
- Fibers and hair
- Rubber and plastic
- Metal
- Underfilled and overfilled containers
- Physical and cosmetic defects
- Blanks

NIST Traceable

Since all particles are measured using equipment verified by a stage micrometer traceable to the National Institute of Standards and Technology (NIST), Sartorius PVS are also useful in the calibration of automated inspection instruments.



Customized Solutions To Meet Your Exact Requirements

Each project is quoted and designed on a customized basis to meet each customer's specific needs. Utilizing our unique project matrix, our clients provide their exact requirements for container type and closure**, fill solution and volume, as well as particulate type, size and number of particles required for each standard.

All particle validation standard kits are assembled by experienced lab technicians using HEPA-filtered laminar flow hoods, Eisai APK container inspection stations, and precision particle sizing traceable to NIST. Certificates of compliance and traceability are included in each kit.

Quality Assurance

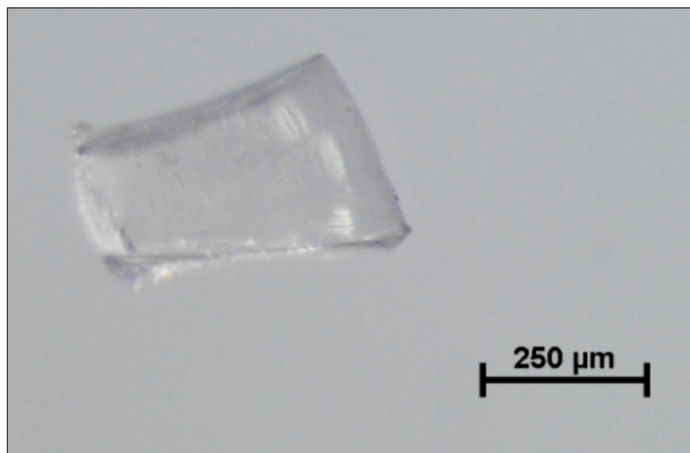
Sartorius quality system is certified to the ISO 9001: Current Version standard.

Standard Fill

Bacteriostatic water is the preferred agent for most projects. HPLC-grade water, custom fills such as liquid drug products and placebos supplied by the customer are available options.

Typical Container Types

Particle validation standards can be created from numerous container types. The most common include vials (1 – 50 mL), dual-chambered vials, ampoules (1 – 20 mL) and syringes.



** To ensure standardization and consistency, SoloHill Particle Validation Standards are processed using customer-supplied containers and sealing components. Rubber stoppers must be Teflon™ coated (or similar) to prevent particle adherence.

Ordering Information

Particle Validation Standards Available for Defect Kits


Particle	Size Range (µm)	Available Sizes (µm) & Notes
Clear glass spheres	100–2000	100–600 (inclusive), 650, 750, 950, and 2000
Black glass spheres	100–1130	Inclusive
Clear polystyrene spheres	100–1000	100–500 (inclusive), 750 and 1000
Black polystyrene spheres	100–500	Inclusive
Red polystyrene spheres	100–500	Request availability
Glass shards	100 +	Amber or clear
Fibers, any color (including clear or fluorescent)	500 +	Recommended to start at 500 µm
Stainless steel shards	100 +	100–1500
Rubber from stoppers plungers	100 +	100 +
Gross underfill overfill	N/A	Volume specified by the customer
Variances in plunger height (syringes)	N/A	Height specified by the customer
Blanks	N/A	N/A
Hair (light, dark or mixed)	500 +	500 +
Cosmetic defects: Glassware Fill solution Sealing Stopper	N/A	Please inquire for details about all available options

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Straße 11
37079 Göttingen
Phone +49 551 308 0

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

 For further contacts, visit
www.sartorius.com