Particle Validation Standards

SoloHill Particle Validation Standards

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

<table>
<thead>
<tr>
<th>Particle</th>
<th>Size Range (μm)</th>
<th>Available sizes (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear glass spheres</td>
<td>100 – 2000</td>
<td>100 – 600 (inclusive), 650, 750, 950, and 2000</td>
</tr>
<tr>
<td>Black glass spheres</td>
<td>100 – 1130</td>
<td>Inclusive</td>
</tr>
<tr>
<td>Clear polystyrene spheres</td>
<td>100 – 1000</td>
<td>100 – 500 (inclusive), 750 and 1000</td>
</tr>
<tr>
<td>Black polystyrene spheres</td>
<td>100 – 500</td>
<td>Inclusive</td>
</tr>
<tr>
<td>Red polystyrene spheres</td>
<td>100 – 500</td>
<td>Request availability</td>
</tr>
<tr>
<td>Glass shards</td>
<td>100 +</td>
<td>Amber or clear</td>
</tr>
<tr>
<td>Fibers, any color (including clear or fluorescent)</td>
<td>500 +</td>
<td>Recommended to start at 500 μm</td>
</tr>
<tr>
<td>Stainless steel shards</td>
<td>100 +</td>
<td>100 – 1500</td>
</tr>
<tr>
<td>Rubber from stoppers</td>
<td>plungers</td>
<td>100 +</td>
</tr>
<tr>
<td>Gross underfill</td>
<td>overfill</td>
<td>N/A</td>
</tr>
<tr>
<td>Variances in plunger height (syringes)</td>
<td>N/A</td>
<td>Height specified by customer</td>
</tr>
<tr>
<td>Cracks in glassware</td>
<td>N/A</td>
<td>Inquire about options</td>
</tr>
<tr>
<td>Blanks</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Hair (light, dark or mixed)</td>
<td>500 +</td>
<td>500 +</td>
</tr>
<tr>
<td>Cosmetic defects</td>
<td>N/A</td>
<td>Glassware</td>
</tr>
</tbody>
</table>
Sales and Service Contacts

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