Form KK-1: Single-Use Technical Communication Guide for Particulate Matter

Introduction

This questionnaire is intended for sharing information between the manufacturers and owners/users regarding the analysis and reporting of particulate matter in single-use components, assemblies and systems. The information provided herein is meant solely as a guide. If additional space is needed to record additional information, please use *Section KK-1-2.7 Additional Comments* on Page 3 or note "See addendum for additional information" in the respective field and attach accordingly.

KK-1.1 General Questions

1. This questionnaire applies to the following: (*please specify product/product group/component/assembly/system/etc*.)

   _____

2. Are the single-use products tested for particulate matter? ☐ Yes *or* ☐ No

3. If yes, what method(s) are used to test for particulate matter? *(choose all that apply)*

   ☐ Visual Inspection Method ☐ Liquid Extraction and Analysis Method ☐ Other (*describe below*)

   _____

KK-1.2 Visual Inspection Method

1. What is inspected? (*check all that apply*)
   - ☐ Product
   - ☐ Package
   - ☐ Other (*describe*): _____

2. Frequency inspected?
   - ☐ 100% of product produced is inspected
   - ☐ A sampling of product produced is inspected (e.g., 1/Lot, AQL, etc.) (specify): _____
   - ☐ Other (describe): _____

3. Visual inspection details (*optional*):

   ☐ Manual *or* ☐ Automated

   Background(s) used: ☐ Black ☐ White ☐ Other (*describe*): _____

   Illumination condition: _____

   Inspection timing: _____

   Inspector qualification: ☐ Yes *or* ☐ No Periodic requalification: ☐ Yes *or* ☐ No ☐ Other (*describe below*)

   _____

4. Is non-conforming product from the visual inspection process investigated? ☐ Always ☐ Sometimes ☐ Never

KK-1.3 Liquid Extraction Method

1. What article(s) is tested?
   - ☐ A product
   - ☐ A representative product (*e.g., master assembly*)
   - ☐ Other (*describe*): _____

2. How often is particulate matter tested for?
   - ☐ At product qualification (*initial/one time/change control*)
   - ☐ Periodically (*check all that apply*): ☐ Yearly ☐ Quarterly ☐ Monthly ☐ Weekly ☐ Daily
   - ☐ Per lot
   - ☐ As requested
   - ☐ Other (*describe*): _____

KK-1.3 Liquid Extraction Method (*cont.*)

3. What is your sampling rate (1/Lot, AQL, other (*explain*))? _____
4. Was the liquid extraction method qualified? ☐ Yes or ☒ No
   a. If yes, was the liquid extraction method qualified according to a standard (*e.g., ASTM E3230-20*)? ☐ Yes *or* ☒ No
   b. If yes, which standard? _____
   c. Which parameters were examined in the qualification? (*choose all that apply*)
      ☐ Nominal/internal volume of the component
      ☐ Agitation type and intensity
      ☐ Rinsing volume
      ☐ Other (*describe*): _____
   d. List any additional information regarding the liquid extraction method (optional):
      _____

KK-1.4 Particle Analysis Method (Counting and Sizing)

1. Was the particle analysis method qualified? ☐ Yes *or* ☒ No (*if no, proceed to Question 2)*
   a. If yes, was the particulate analysis method qualified according to a standard (*e.g., USP<788>*)? ☐ Yes *or* ☒ No
   b. If yes to 1a, which standard? _____
   c. If the particulate analysis method was qualified to USP<788>, which specific method was used?
      ☐ USP<788> Method 1: Light Obscuration Particle Count Test *or* ☐ USP<788> Method 2: Microscopic Particle Count Test
   d. If a technique described in the USP<1788> guidance was applied, please select which one?
      ☐ USP<1788.2> Membrane Microscope Method Section 6: Automated Approaches *or* ☒ USP<1788.3> Flow Imaging Method
2. Were other particle analysis techniques applied? ☐ Yes *or* ☒ No
   a. If yes, please explain: _____
   b. If yes, how was this other particle analysis method qualified?
      ☐ According to guidance in USP <1788>
      ☐ External accredited laboratory
      ☐ Other (*describe*): _____

KK-1.5 Particle Analysis Method (Identification)

1. Are methods for particle identification applied? ☐ Yes *or* ☒ No
   a. If yes, how are the particles identified and classified? (choose all that apply)
      ☐ Chemical attributes (*e.g. spectroscopic identification*)
      ☐ Physical attributes (*e.g. shape, morphology, refractive index*)
      ☐ Other (*describe*): _____
   b. In what situations are particles identified? (choose all that apply)
      ☐ Corrective Actions/Preventative Actions (CAPA)
      ☐ Continuous Improvement efforts

☐ Out of specification situations

☐ Other (*please describe*): _____

KK-1.6 Data Analysis and Reporting

1. How are the particle count/size data analyzed? _____
2. Are the particle count/size data analyzed and reported according to USP<788>? ☐ Yes *or* ■ No
3. What particle size classification is used?
   - ☐ Sub-visible particle count ≥ 10 µm
   - ☐ Sub-visible particle count ≥ 25 µm
   - ☐ Visible particle count ≥ 100 µm
   - ☐ Other (*please describe*) _____
4. If data are reported per volume (mL), which volume is used in the reporting?
   - ☐ Interior volume of the single-use product
   - ☐ Volume of liquid applied in the extraction method (*please specify volume*) _____
   - ☐ Other volume (*describe*) _____
5. What, if any, additional information is reported? (choose all that apply)
   - ☐ Particle count for other particle size ranges
   - ☐ Particle count per surface area: (*choose all that apply*)
     - ☐ Interior surface area of product
     - ☐ Exterior surface area of product
     - ☐ Particle count per product
     - ☐ Extraction effectiveness (*see ASTM E3230-20*)
6. Are there product release criteria based upon particle counts for a specified particle size range? ☐ Yes *or* ■ No
   a. If yes, are the criteria based upon the USP<788> large volume parenteral specification? ■ Yes *or* ☐ No
   b. Are there other criteria? (*please describe*) _____
7. Are the particles data trended (*e.g., control charts*)? ☐ Yes *or* ■ No
8. Are particle source identification and preventative actions (continuous improvement) applied? ■ Yes *or* ☐ No
   a. If yes, provide criteria, if applicable (*e.g., size, type of particle*) _____

KK-1.7 Additional Comments