Being particulate about sterile vials:
Technique, tips and visual inspection done right

Mark Filosi, BS Pharm, RPh

Compounding Coach, MAZ Ecosystem

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Mark Filosi, BS Pharm, RPh

Mark Filosi, BS Pharm, is a distinguished graduate of the Massachusetts College of Pharmacy in Boston. He is the owner of Family Care Pharmacy and Live and Learn Pharmacy. With extensive experience in the field, Mark has served as a career coach and preceptor for numerous universities. He has also held the position of surveyor for the Pharmacy Compounding Accreditation Board (PCAB)/Accreditation Commission for Health Care (ACHC).

Currently, Mark contributes his expertise as a member of the Board of Directors for the Alliance for Pharmacy Compounding. In his current professional capacity, he serves as a compounding coach for the MAZ ecosystem at Medisca, where he continues to advance the field of pharmacy compounding.

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Understanding Particulate Contamination

- Why is this important?
  - Particulate contamination in sterile compounding can compromise drug safety and quality.
  - Regulatory bodies set strict guidelines to ensure patient safety.
- Types of Particulate Contamination:
  - Intrinsic: Comes from materials used (e.g., vial stoppers, tubing).
  - Extrinsic: Comes from the environment (e.g., dust, lint).

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Regulatory Standards & Inspection Methods

- Two Common USP Inspection Methods:
  - USP <788>: Particulate Matter in Injections – Particulate Matter in Injections test is used to quantify the count and size of subvisible particles in parenteral drugs.
  - USP <790>: Visible Particulates in Injections – All products intended for parenteral administration must be visually inspected for the presence of particulate matter as specified for Injections.
- ISO Standard for Empty Sterile Vials:
  - ISO 8362-7: Covers quality and specifications for empty sterile vials.

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Best Practices for Needle Use to Prevent Coring

- Use No-Coring Needles:
  - Recommended brands include BD Nokor, Terumo SurGuard, Monoject non-coring and others.
- Proper Needle Handling:
  - Insert the needle at the correct angle to avoid cutting rubber particles from the stopper.
  - Limit needle reuse:
    - Lubricant can wear off from stopper
    - Needle bevel can become dull

Best Practice

- Disinfect the stopper with an alcohol swab.
- Position the syringe-to-needle assembly at a 45° to 60° angle with the **needle bevel face up** and centered in the circle of the stopper.
- In one clean motion, apply a slight downward pressure on the bevel while quickly rotating the syringe-to-needle assembly to a position perpendicular to the stopper as the needle enters the vial.

Tips

- Visually inspect the vial for fragments (aka cores) of the stopper.
  - If fragments are detected, then filter or discard the fluid, whichever may be deemed appropriate.

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Other Potential Sources of Particulates

- Beyond the Vial:
  - Particulates can come from fluid transfer or septum of an IV bag not just the vial or stopper.
- Root Cause Analysis Approach:
  - Identify all potential contamination points in the compounding process.
  - Consider operator technique, tubing, filters, and vial handling.

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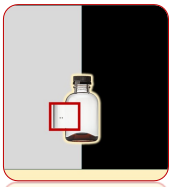
Testing for Particulates – Practical Approach

How to check if a preparation contains particulate**:

1. Aseptically process final container-closures (e.g., vials).
2. Use sterile tweezers to stopper the vials.
3. Transfer stoppered vials out of the ISO class 5 PEC.
4. Crimp an appropriate number of vials for particulate testing.
5. Tilt each sample vial back and forth 20 times to simulate agitation, and then inspect as per USP <790>:
   - Inspect each vial for visible particulates.
   - Qualified third-party independent lab recommended in cases where Category 3 CSPs are prepared once per formulation with acceptable results.

** This procedure may require modification when adding it to an approved Master Formulation Record.



Best Practice: Use a device comprised of a contrast background, half white and half black, with a fluorescent light source shining upward into the container closures to best visualize particulate or any other foreign matter, discoloration, or defects.

Further augment your visual inspection capability using a magnifying glass.

If the CSP is prepared under Category 3 conditions, and extending to a longer BUD, and is an injection or ophthalmic solution, additional particulate-matter testing as per USP <797>, 2023 must be conducted once per formulation with acceptable results.

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Contact Information

Mark Filosi, BS Pharm, RPh

Compounding Coach, MAZ Ecosystem

mfilosi@medisca.com

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