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Media Fill Testing

A media fill test is required by United States Pharmacopeia (USP) and state boards of pharmacy to prove that the aseptic technique process can produce a sterile product without contamination. According to USP <797>, any person engaged in sterile compounding must conduct a media fill test:

- Before beginning sterile compounding for three consecutive days to simulate repetitive process competency.
- At least annually for low to medium risk compounding.
- At least semi-annually for high-risk compounding.

Personnel should perform the media fill test under the most stressful and challenging conditions at the pharmacy.

Media fills use sterile microbiological growth media in place of the drug product and simulates all production operations including:

- Preparation and assembly of product containers
- Transfer of product to the fill area
- All process steps downstream from the sterilizing filter up to product release including packaging into finished product containers

The most common growth media is soybean casein digest medium (SCDM), which is also known as Trypticase Soy Broth. Pharmacists can make their own media using USP recipes as long as they comply with the requirements of growth promotion and sterility testing. Pharmacists may also buy media from a qualified vendor. A vendor is qualified by testing three batches of media using quality control tests: growth promotion, pH, sterility and visible inspection.

The media fill process should include controls. A positive control is a sealed product container of media inoculated with a small number of microorganisms. If growth occurs, the positive control demonstrates the media can promote growth of the organism(s). A negative control is prepared by transferring media into a separate sterile container and incubating the control with media fill test containers. The negative control should not show microorganism growth proving the media was sterile at the start.

After completing the media-fill preparation, personnel should sample gloved fingertip and thumb (without applying sterile 70% IPA) from both hands onto sterile contact agar plates to check the competency of aseptic work practices.

Samples and controls are incubated at appropriate temperatures for media used. Examples include:

- 20°C to 25°C or at 30°C to 35°C for at least 14 days; or,
- Filled containers are incubated for at least 7 days at each temperature.

The plates are incubated for 30°C to 35°C for 48 to 72 hours.

A positive media fill test indicates microbial growth is present and can reveal:

- Compounding employee needs more training
- Compromised controlled cleanroom environment
- Compromised integrity of sterilizing filter

A negative media fill test indicates no growth is present. It does not mean that products are free of contamination. The media fill test frequency as required by USP and state boards of pharmacy is minimal compared to other quality testing frequency requirements. In addition to media fill testing, it is important to have stringent quality standards and procedures in place to support a reliable and robust sterile compounding program.

If you would like ARL to incubate your media fill samples or for more information about media fill testing, contact ARL at 800-393-1595 or info@arlok.com.