Particulate contamination of parenteral fluids is a fact of life. Particulate infusion is unlikely to cause immediate or severe signs and symptoms, but adverse effects, tissue damage, and loss of function are likely in the long term” Zarour-Shalev et al (2015).

Abstract:

One major current challenge facing companies producing injectable drugs contained in glass vials is the phenomenon of delamination that results in drug contamination. Particulate contamination of parenteral fluids is a fact of life. Particulate infusion is unlikely to cause immediate or severe signs and symptoms, but adverse effects, tissue damage, and loss of function are likely in the long term.

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Since 2010, recalls due to glass delamination have increased, and recently the U.S. Food and Drug Administration exercised temporary regulatory flexibility by allowing filtration as means of removing glass particles. The vial adapter is a needle-free product from West Pharmaceuticals Services that provides a simple and cost-effective solution for the safe and rapid transfer reconstitution of drugs between vials and syringes. One variant of the vial adapter is integrated with a filter to address various types of particles. In the present study,
the performance of the filter-integrated vial adapter is evaluated with respect to glass delamination particles. Silica particles of 0.5-10 μm are used to emulate glass delamination particles. High-filtration efficiency is demonstrated according to the severest criteria stated by the British Pharmacopoeia that allows up to 100 particles smaller than 5 μm for every 1 mL liquid of a large-volume parenteral. The study was conducted using environmental scanning electron microscopy and statistical analysis.

LAY ABSTRACT: One major current challenge facing companies producing injectable drugs contained in glass vials is the phenomenon of delamination that results in drug contamination. Glass delamination is defined as degradation of surface glass, as from a vial, that produces glass flakes. Contamination of injectable drugs due to glass delamination is a fact of life. Normally, this type of contamination does not involve immediate severe signs, but rather accumulative damage to tissues in the long run. Recently, the U.S. Food and Drug Administration allowed the filtration as means of removing particles. The vial adapter is a needle-free product from West Pharmaceuticals Services that provides a simple and cost-effective solution for the safe and rapid transfer reconstitution of drugs between vials and syringes. One variant of the vial adapter is integrated with a filter to address various types of particles. In the present study, the performance of the filter-integrated vial adapter is evaluated with respect to glass delamination particles. Silica particles of 0.5-10 μm are used to emulate glass delamination particles. High-filtration efficiency is demonstrated according to the severest criteria stated by the British Pharmacopoeia that allows up to 100 particles smaller than 5 μm for every 1 mL liquid of a large-volume parenteral. The study was conducted using environmental scanning electron microscopy and statistical analysis.

Reference:


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