



## 50 Percent Magnesium Sulfate Injection, USP by Hospira: Recall – Presence Of Particulate Matter” FDA (2016).

FDA report “Hospira, Inc. is voluntarily recalling one lot of 50% Magnesium Sulfate Injection, USP, 10 g/20 mL (0.5 g/ml), 20 mL Single-dose vials, Lot 50-343-DK, Expiration 01FEB2017, NDC 0409-2168-02, to the hospital level due to a confirmed customer complaint for the presence of particulate matter, within one single-dose fliptop vial. A recall was previously executed for this lot on March 23, 2016 due to a confirmed high out of specification (OOS) result for pH.

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If the particulate is detected prior to dispensing or administration to a patient, patient harm is unlikely. If the delay of therapy is prolonged, there is the potential for serious medical consequences for mother and fetus requiring medical intervention. If the particulate is not observed prior to administration, it may result in localized swelling, redness, pain at the site of administration or veins, allergic reactions to the foreign particle, microembolic effects as well as possible fetal harm. The likelihood of serious patient harm is considered low due to high-detectability of this non-conformance.”

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProduct>



s/ucm496149.htm

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