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Hospira recalls propofol injectable due to visible particulates in vial

21 April 2014 | Regulatory | By BioSpectrum Bureau

Singapore: Hospira has issued a nationwide recall of seven lots of Propofol Injectable Emulsion to the user level due to a glass defect located on the interior neck of the vial, which was identified during a retain sample inspection where the glass vial contained visible embedded metal particulate. Free-floating metal particulates were also identified in vials upon further analysis.

In general, injected particulate matter may result in local inflammation, phlebitis, and/or low level allergic response through mechanical disruption of tissue or immune response to the particulate. Capillaries, which may be as small as the size of a red blood cell, may become occluded. Chronically, following sequestration, particulate matter may lead to granulomatous formation, most likely in the lungs. Long term clinically meaningful impact is low if a patient has normal lung function. While extremely rare, embedded stainless steel may put a patient at risk from MRI (strong magnetic field exposure) as particulate, if in the lung, could potentially dislodge and be pulled through tissue.

The affected lots were distributed in US to distributors/wholesalers, hospitals and clinics from August 2013 through December 2013.