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Mylan injections found with foreign material

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Singapore: Global pharmaceutical company, Mylan, has run into a trouble for the presence of visible foreign material in injectable products. The company is consequently recalling the affected products from hospitals and user level, all distributed in US.

One of the recalled product, Cytarabine Injection, was manufactured and packaged by Agila Onco Therapies, a Mylan company located in Bangalore, India and is packaged with a Pfizer Injectables label.

Administration of a sterile injectable that has foreign particulates has the potential of severe health consequences. Intrathecal administration could result in a life threatening adverse event or result in permanent impairment of a body function. Intravenous administration has the potential to damage and/or obstruct blood vessels which could induce emboli, particularly in the lungs.

Products in question include Gemcitabine for injection, an intravenously administered product indicated for the treatment of ovarian cancer, breast cancer, non-small cell lung cancer and pancreatic cancer; Methotrexate Injection indicated for certain neoplastic diseases, severe psoriasis and adult rheumatoid arthritis; and Cytarabine Injection indicated for remission induction in acute non-lymphocytic leukemia of adults and pediatric patients.