BioSpectrum
the business of Bio & Health Sciences

Aurobindo Pharma's arm voluntarily recalls two antibiotic injections

15 May 2018 | News

To date, AuroMedics Pharma LLC has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from these lots.

AuroMedics Pharma LLC, a US subsidiary of Aurobindo Pharma Ltd has initiated voluntary recall of two lots each of two injections from the US market following customer complaints about presence of particles in the vial.

The fresh recall follows a recent withdrawal of over 1.5 million injections by the company due to “Lack of Assurance of Sterility.”

According to a letter issued to the US Food and Drug Administration department, the recall of Ampicillin and Sulbactam for injection, USP, Single-Dose vial, to the hospital has been initiated due to customer complaints of the presence of red particulate matter in the product.

Two lots of Piperacillin and Tazobactam for injection, USP 3.375 g (Piperacillin Sodium equivalent to 3 g of Piperacillin USP and Tazobactam Sodium equivalent to 0.375 g of Tazobactam USP are being recalled. Each vial contains 7.05 mEq (162 mg) of Sodium) in a Single-Dose vial, to the hospital level. The products have been found to contain particulate matter, visible only after reconstitution that was confirmed to be glass within the vial.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening.

To date, AuroMedics Pharma LLC has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from these lots.

“Piperacillin and Tazobactam for Injection is used for treatment of patients with moderate to severe infections caused by susceptible isolates of the designated bacteria in intra-abdominal, skin and skin structure and female pelvic infections as well as community acquired and nosocomial pneumonia,” said a statement.

It is packaged in a carton containing 10 single- dose vials. “The product can be identified as a clear vial stoppered with grey rubber stopper and sealed with aluminum seals having a Royal Blue color polypropylene disc,” a statement issued by FDA

stated further.