Title: Significant research on meropenem cross-contamination management in a β-Lactam manufacturing unit: A high-performance liquid chromatography approach.

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Abstract: Rapid, simple, and sensitive high-performance liquid chromatography with diode-array detection (HPLC-DAD) techniques are described for quantitatively determining meropenem residue from the contact parts of injection filling machines. This involves swab sampling collected after cleaning. The method also addresses the management of meropenem cross-contamination in shared cephalosporin production facilities. Cross-contamination is the product mix-up by which a trace amount of antibiotics can be present in other products that cannot prevent infections but can contribute to initiating antibiotic-resistant pathogens into human microflora. Poor beta-lactam contaminant control can cause residual Meropenem in different dosage forms, resulting in meropenem residue in the human intestinal flora, blood during sepsis, or Environmental wastes. During manufacturing, there should be a validated scientific control with proper monitoring of meropenem contamination. Meropenem residue was determined on the contact parts of production machines using swab sampling collected from surfaces after cleaning. An isocratic chromatographic system used with a mobile phase consisting of acetonitrile: 20% tetrabutylammonium hydroxide adjusted to pH 6.5 ± 0.05 (30:70, v/v) on XTerra RP18 column at a flow rate 1.0 mL min-1 with an injection volume, 20 µL and UV (290 nm). HPLC-DAD method developed was found to be linear (R2 ≥ 0.999), sensitive, precise (RSD < 2.7%), accurate (recovery between 97% and 109%), and LOD and LOQ were obtained at 0.05 and 0.10 mg L-1, respectively. The area RSD (%) for six replicate injections of LOQ was 7.6. This study validated the Meropenem contaminant controlling procedure for drug manufacturers.

Keyword: Meropenem, High-Performance Liquid Chromatography, Antibiotic Resistance, Cross-Contamination, Drug Manufacturing Unit, Microflora.

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