In this study, development of the tri-amino acid buffered solithromycin intravenous (IV) formulation was performed to minimize the occurrence of infusion associated local adverse events (infusion site pain or phlebitis) observed in patients who received the tartaric acid buffered IV formulation with a lower buffered capacity during Phase I clinical trials” Evans et al (2017).

Abstract:

Solithromycin is a fluoro-ketolide (a fourth-generation macrolide) antibiotic that has been undergoing clinical trials for the treatment of community acquired bacterial pneumonia. In this study, development of the tri-amino acid buffered solithromycin intravenous (IV) formulation was performed to minimize the occurrence of infusion associated local adverse events (infusion site pain or phlebitis) observed in patients who received the tartaric acid buffered IV formulation with a lower buffered capacity during Phase I clinical trials. Development of the tri-amino acids buffered solithromycin IV formulation was achieved using a dynamic in vitro precipitation model. Computational modeling also supports the superiority of the amino acid buffered formulation over the tartaric aid buffered formulation.

Reference:


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