

Industrial & Molecular Pharmaceutics Seminar

IMPH 69600

Monday, March 4, 2024
4:30 PM in RHPH 164

“Advanced Characterization of Ferric Carboxymaltose (Injectafer®)”



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First Seminar

Injectafer® (ferric carboxymaltose, FCM) is an FDA-approved, high molecular weight intravenous (IV) iron-carbohydrate complex that is widely used for the treatment of iron deficiency anemia in the U.S. The carboxymaltose ligands, which are derived from maltodextrin, strongly interact with the polynuclear iron (III)-oxyhydroxide/oxide core and thus stabilize the iron core and provide for the controlled release of iron. FCM's characteristic properties include higher bioavailability, maximum dosing, shortest administration time, longer half-life, and almost no transferrin oversaturation compared to other controlled release forms of iron. Carboxymaltose variability, such as the source, molecular weight, heterogeneity, and oxidation mechanism, significantly affect the physicochemical properties of carbohydrate ligands and, subsequently, the drug substance. In addition to the inherent challenges associated with high molecular weight iron complexes, the FDA guidelines of API sameness for IV iron complexes make it more difficult for generic companies to formulate a generic version of FCM. The primary purpose of this study is to determine in Injectafer® the structure of carboxymaltose, the structure of the iron core, and how the carboxymaltose interacts with the iron core. The results will provide valuable information to the generic companies to bring a generic version of FCM with improved dosage form and at a reduced cost to market.