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Bioequivalence decision for nanoparticular iron complex drugs for parenteral administration based on their disposition

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1. Abstract

Although parenteral iron products have been established to medicinal use decades before, their structure and pharmacokinetic properties are not fully characterized yet. With its' second reflection paper on intravenous iron-based nano-colloidal products (EMA/CHMP/SWP/620008/2012) the European Medicine Agency provided an extensive catalogue of methods for quality, non-clinical and pharmacokinetic studies for the comparison of nano-sized iron products to an originator (EMA, 2015). For iron distribution studies, the reflection paper assumed the use of rodents. In our tests, we used a turkey