

Accepted Manuscript

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

Julia Schnorr, Sören Fütterer, Karsten Spicher, Maria Catarinolo, Christoph Schlösser, Harald Enzmann, Peter Langguth



PII: S0273-2300(18)30054-0

DOI: [10.1016/j.yrtph.2018.02.009](https://doi.org/10.1016/j.yrtph.2018.02.009)

Reference: YRTPH 4066

To appear in: *Regulatory Toxicology and Pharmacology*

Received Date: 12 May 2017

Revised Date: 29 January 2018

Accepted Date: 12 February 2018

Please cite this article as: Schnorr, J., Fütterer, Sö., Spicher, K., Catarinolo, M., Schlösser, C., Enzmann, H., Langguth, P., Bioequivalence decision for nanoparticular iron complex drugs for parenteral administration based on their disposition, *Regulatory Toxicology and Pharmacology* (2018), doi: 10.1016/j.yrtph.2018.02.009.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

1 **Bioequivalence decision for nanoparticulate iron complex**
2 **drugs for parenteral administration based on their**
3 **disposition**

4 Julia Schnorr¹, Sören Fütterer¹, Karsten Spicher², Maria Catarinolo², Christoph
5 Schlösser², Harald Enzmann², Peter Langguth¹

6 ¹ Institute for Pharmaceutical Technology and Biopharmacy, Johannes
7 Gutenberg-University, Mainz

8 ² Federal Institute for Drugs and Medical Devices (BfArM), Bonn

9 **Keywords:** Nanomedicine, Non-biological complex drugs, Iron, Tissue
10 distribution, Organotropy, Essential similarity, Bioequivalence

11 **1. Abstract**

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

Download English Version:

<https://daneshyari.com/en/article/8551506>

Download Persian Version:

<https://daneshyari.com/article/8551506>

[Daneshyari.com](https://daneshyari.com)