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Fed and fasting bioquivalence study for two formulations of bosentan 125 mg tablets in healthy Colombian people

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This is a pharmacokinetic study of two formulations containing Bosentan 125 mg, in order to compare the bioavailability between the Test product (Bosentan produced by Tecnoquímicas S.A. laboratory, Colombia) and the Reference product (Tracleer® produced by Actelion Pharmaceuticals) in fasting and fed conditions, in order to state the bioequivalence between them. For this, an open label, four periods, two randomized sequences, crossover, with single pre- and fed 125 mg dose study was performed in 30 healthy volunteers, with an 8-day washout period between each period and a collection of 14 plasma samples between 0 and 24 hours. Identification and evaluation of Bosentan in plasma was carried out by ultra high-performance liquid chromatography-tandem mass spectrometry UHPLC/MS/MS as analytical method. Based on the European and FDA bioequivalence research guidelines, the CI falls within the allowed ranges for the Bioequivalence and Interchangeability Statement of the Tecnoquímicas S.A. product with the Reference product. Both formulations had similar pharmacokinetic parameters in each studied condition, fed and fasted. Moreover, an increase in the amount of active pharmaceutical ingredient is evident in fed conditions.

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Enabling rational design and development of nano-medicines: The nano-assemblerTM platform

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In the past decade a considerable progress in understanding the interaction of organisms. With nano-medicine was achieved. While exciting discoveries are made in the research field, the translation of Nanomedicine from the bench to clinics remains challenging, notably due to the fact that incumbent formulation methods for producing Nanomedicine are labour-intensive, inconsistent and difficult to scale up. Moreover, the lack of control over some of the most basic characteristics of nanoparticles, size and polydispersity limit the ability to rationally design *in vitro* and *in vivo* studies. Here we introduce the NanoAssemblr™ Platform, which uses custom engineered microfluidic cartridges to perform nanoprecipitation within milliseconds and nanoliter reaction volumes. This enables well controlled, bottom-up self-assembly of nanoparticles such as RNA lipid nanoparticles, liposomes and polymeric nanoparticles with tunable sizes and low poly dispersity in one single step. Full automation of the system allows for high reproducibility of batches and excellent transferability of protocols between users. Varying parameters, such as total flow rate or flow ratio of the fluids, in the microfluidic channel can allow control over the size and polydispersity of the resulting nanoparticles, e.g. liposomes. The NanoAssemblr™ Benchtop Instrument facilitates rapid formulation screening at volumes between 1-15mL making it ideal for low-cost formulation and process development. Prototype formulations are easily scaled-up with the Nano Assemblr™ Scale Up Device, which uses parallel microfluidic mixers. Incorporating multiple mixers into a single microfluidic chip increases the throughput while maintaining identical reaction conditions. This technique allows for massive parallelization to achieve production scales from milliliters to litres.

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