Gustavo D Mendes, J Bioequiv Availab 2014, 6:5
http://dx.doi.org/10.4172/0975-0851.S1.019

OMICS Group Conferences
Accelerating Scientific Discovery

5th World Congress on
Bioavailability and Bioequivalence
Pharmaceutical R&D Summit

September 29-October 01, 2014 DoubleTree by Hilton Baltimore-BWI Airport, USA

Pharmacokinetics and pharmacodynamic evaluation of a nanotechnological topical formulation of lidocaine/prilocaine (nanorap) in healthy volunteers

Gustavo D Mendes
University of Sao Francisco (USF), Brazil

Nanorap is a new nanotechnological formulation for topical anesthesia composed of lidocaine (2.5%) and prilocaine (2.5%). The pharmacokinetics of Nanorap was evaluated after topical application of 2 g to healthy volunteers. For this evaluation a new simple, selective and sensitive method for the determination of lidocaine and prilocaine in human plasma was developed. The method was based on high-performance liquid chromatography coupled to tandem mass spectrometry (HPLC-MS/MS) using ropivacaine as internal standard. The drugs were extracted from plasma by liquid-liquid extraction with ether/hexane (80/20, v/v). The chromatography separation was performed on a Genesis C18 analytical column 4 µm (100 x 2.1 mm i.d.) with a mobile phase of methanol/acetonitrile/water (40/30/30, for lidocaine, and 50/30/20, for prilocaine, v/v/v) + 2 mM of ammonium acetate. The method had a chromatography run time of 5.5 min for lidocaine and 3.3 min for prilocaine and a linear calibration curve over the range 0.05 - 10 ng/mL for both drugs. The lower limit of quantification (LLOQ) was 0.05 ng/mL for both drugs. The precision and accuracy values of the assays were within ±10%. The stability tests indicate no significant degradation under conditions of experiment. The drugs were quantified using a mass spectrometer with an electrospray source in the ESI positive mode (ES+) configured for multiple reaction monitoring (MRM). Mean Cmax for lidocaine was 6.62 ng/mL. Mean Cmax for prilocaine was 1.72 ng/mL. Median Tmax was 6.5 hours for both drugs. Nanocapsule suspension was evaluated and Nanorap was characterized by cryofracture, showing a mean drug association of 92.5% and 89% for lidocaine and prilocaine, respectively. Nanocapsules had a mean size of 88nm. The pharmacodynamics (PD) of Nanorap was evaluated with the use of a visual analogue scale. The PD study showed that Nanorap has a sufficient analgesic effect (>30% reduction in pain) after 10 minutes of application.

Biography

Gustavo D Mendes is Professor of Department of Surgery, Faculty of Odontology, University of Sao Francisco (USF), Braganca Paulista, SP, Brazil and Department of Surgery, Faculty of Odontology, University Camilo Castelo Branco (UNICASTELO), São Paulo, SP, Brazil. He has published more than 46 papers in reputed journals.t

mendesgd@yahoo.com.br