OMICS International
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Thaisa M Dezani et al., J Bioequiv Availab 2015, 7:5
http://dx.doi.org/10.4172/0975-0851.S1.022

6th World Congress on
Bioavailability & Bioequivalence:
BA/BE Studies Summit

August 17-19, 2015 Chicago, USA

A rapid HPLC method for ranitidine quantification: Application for *in situ* intestinal perfusion studies

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Absorption prediction of drugs has been grown in recent years and studies involving *in vivo, ex vivo* and *in situ* methods are applied for permeability assessment of substances. Single-Pass Intestinal Perfusion (SPIP) is a technique employed for absorption studies prediction using an intestinal segment. This work aims to show a chromatographic method developed and validated for ranitidine (RNT) quantification from perfusate samples. A simple, precise, specific and accurate RP-HPLC (reversed-phase high performance liquid chromatography) method was developed and validated for RNT using ICH guideline considering parameters as selectivity/specificity, linearity, precision, accuracy, limit of detection and limit of quantification. The chromatographic conditions were achieved with: Gemini C18 column (150 mm x 4.6 mm x 5 µm), ultraviolet detection at 315nm (RNT) and 270 nm (zidovudine as internal standard), oven set at 30°C. The mobile phase consisted of phosphate buffer 10 mM, methanol and acetonitrile (65:30:5) pH 7.2, flow of 1 mL/min and injection volume of 75 µL. The assessed parameters were in accordance with the recommendations. The method presented linearity in a range of 5-150 µg/mL (r^2=0.9999). Precision and accuracy are also adequate with intraday and interday variation below 5%. No interferences were noticed in chromatograms, reflecting the selectivity and specificity of the method. The chromatographic method was developed and validated for RNT quantification in perfusate samples and its applicability in daily lab routine is possible. Also, this method can be useful for development of other chromatographic methods in SPIP studies, especially in co-perfusion situation. This study had financial support by FAPESP, CAPES and CNPq (Brazil).

Biography

Thaisa M Dezani has completed her Master's degree in 2012 and since then, she is developing her PhD thesis related to permeability studies using different methods as *in situ, ex vivo* and *in vitro* models. Her research field also includes solubility, biopharmaceutical classification systems, dissolution studies and ADME prediction. The studies are conducted in Faculty of Pharmaceutical Sciences of University of Sao Paulo, Brazil.

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