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A rapid HPLC method for metoprolol quantification: Application for *ex vivo* intestinal studies using Franz cells

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An important factor for the good bioavailability of a drug is the complete absorption and studies involving this prediction have been grown in recent years. Among several studies, *ex vivo* methods using vertical diffusion chamber (Franz cells) experiments have gained highlight for permeation studies. This method employs an intestinal segment and it can be used for biowaiver purposes. This work aims to show a chromatographic method developed and validated for quantification of metoprolol contained in samples obtained from *ex vivo* assays using Franz cells. A simple, precise, specific and accurate RP-HPLC (reversed-phase high performance liquid chromatography) method was developed and validated 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 (250 mm x 4.6 mm x 5 µm), fluorescence detection set at 225 nm for excitation and 310 nm for emission, oven set at 35°C. The mobile phase consisted of a mixture of phosphate buffer 20 mM and acetonitrile (80:20%) pH 4.5, flow of 1 mL/min and injection volume of 25 µL. The assessed parameters were in accordance with the ICH recommendations. The method presented linearity in a range of 10-1000 ng/mL (r^2=0.9993). Precision and accuracy are also adequate with intraday and interday variation no higher than 5%. During development and validation, no interferences were noticed in chromatograms, showing the selectivity and specificity of the method. The chromatographic method was developed and validated for metoprolol quantification in samples from Franz cells assay and its applicability in daily lab routine is possible for permeation studies with several kinds of biological tissues, including intestine. Also, this method can be useful for development of other chromatographic methods in similar studies.

Biography

Andre B Dezani has completed his Master's degree in 2010 and since then, he is developing his PhD thesis related to permeability studies using different methods as *ex vivo* and *in vitro* models. His 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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