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Resumo	There are many hurdles in the development of generic formulations. In vitro biopredictive dissolution conditions together with alternative in vitro - in vivo relationship (IVIVR) approaches can be a powerful tool to support the development of such formulations. In this study, we hypothesized that the release profile of enteric coated (EC) formulations of pantoprazole in physiologically relevant bicarbonate buffer (BCB) would detect possible performance differences between test and reference formulations resulting in more accurate IVIVR results and predictability when compared to a pharmacopeial dissolution test. We correlated the in vitro performance of test and reference formulations (both in BCB and pharmacopeial phosphate buffer) with the in vivo data from a failed bioequivalence study. Test and reference formulations of EC pantoprazole tablets passed the USP dissolution criteria. However, they failed statistical similarity in vitro both in compendial and BCB. Bicarbonate buffer was additionally more discriminative while being more physiologically relevant. Having BCB as an additional test to evaluate EC products in vitro might improve the comparison of formulations. This can de-risk the development of generic EC formulations.
Fomento	