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Título	In Vivo Predictive Dissolution (IPD) for Carbamazepine Formulations: Additional Evidence Regarding a Biopredictive Dissolution Medium
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Resumo	The aim of the present study was to bring additional evidence regarding a biopredictive dissolution medium containing 1% sodium lauryl sulphate (SLS) to predict the in vivo behavior of carbamazepine (CBZ) products. Twelve healthy volunteers took one immediate release (IR) dose of either test and reference formulations in a bioequivalence study (BE). Dissolution profiles were carried-out using the medium. Level A in vitro–in vivo correlations (IVIVC) were established using both one-step and two-step approaches as well as exploring the time-scaling approach to account for the differences in dissolution rate in vitro versus in vivo. A detailed step by step calculation was provided to clearly illustrate all the procedures. The results show additional evidence that the medium containing 1% SLS can be classified as a universal biopredictive dissolution tool, and that both of the approaches used to develop the IVIVC (one and two-steps) provide good in vivo predictability. Therefore, this biopredictive medium could be a highly relevant tool in Latin-American countries to ensure and check the quality of their CBZ marketed products for which BE studies were not requested by their regulatory health authorities.
Fomento	