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| Título | In Vitro-In Vivo Correlation for Desvenlafaxine Succinate Monohydrate Extended Release Tablets |
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| Resumo | The objective of this study was to develop a dissolution test in order to establish an *in vitro–in vivo* correlation (IVIVC) model for desvenlafaxine succinate monohydrate (DVSM) extended release (ER) tablets. The *in vitro* release characteristics of the drug were determined using USP apparatus 1 at 75 rpm, with volume of HCl pH 1.2, acetate buffer solution (ABS) pH 4.5, or phosphate buffer solution (PBS) pH 6.8. *In vivo* plasma concentrations and pharmacokinetic parameters in healthy volunteers were obtained from a bioequivalence study. The similarity factors $f_1$ and $f_2$ were used to compare the dissolution data. The IVIVC model was developed using fraction dissolved and fraction absorbed of the reference product. For predictability, the results showed that the percentage prediction error (%PE) value of $C_{max}$ was 7.63%. The observed low prediction error for $C_{max}$ demonstrated that the IVIVC model was valid for this parameter. |
| Fomento | |