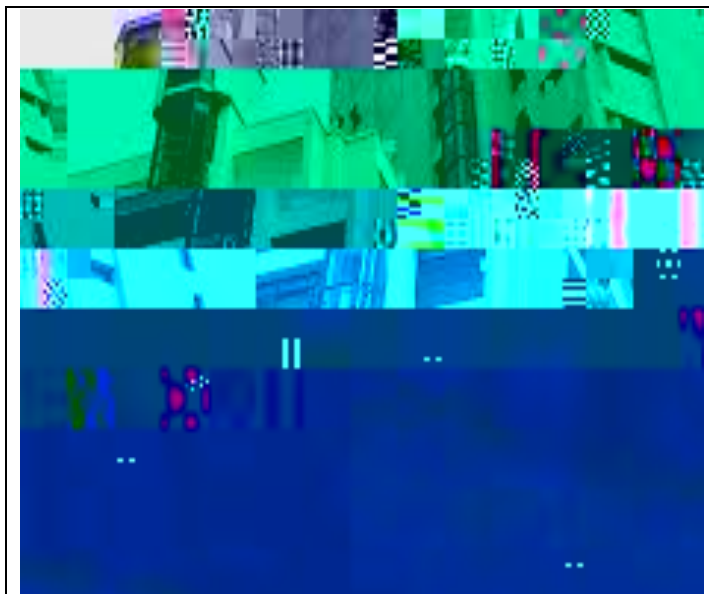


The solubility measurements of crystallized Ibuprofen at low ethanol contents with aqueous co-solvents of excipients

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ABSTRACT: The objective of this study was to determine the effect of five pharmaceutically used excipients e.g. L-lactose, hydroxy propyl methyl cellulose (HPMC)1, leucine, D-mannitol and Pluronic F127 (PI F127) on the ibuprofen (Ibu) solubility in water (W) - ethanol (E) co-solvent systems. The solubility was measured in water (W) - ethanol (E) mixtures from 0 to 50% w/w ethanol at 10, 25 and 40 °C by the dissolution method using UV spectrophotometry. The Ibu solubility without excipients in water (zero ethanol) was low (~ 50 ppm); however, increased near exponentially with increasing ethanol content. The maximum solubility of Ibu (1726 ppm) was observed in a solvent containing 1.52% leucine, 5.22% mannitol, 0.25% HPMC, 1.55% PI F127 and 10.75% w/w ethanol. At 40 °C, there was phase separation between 34% and 63% w/w E/(E+W). Individually, the effect of PI F127 showed significant influence on enhancing the solubility of Ibu and lactose showed a linear increase of Ibu aqueous solubility (slope ~1200). The effects of individual leucine, mannitol and HPMC on Ibu solubility were limited; however, the combination of these excipients raised Ibu solubility very high. The solubility effect of these excipients is important in designing the crystallization technique for Ibu with enhanced solubility at low ethanol content. Study of ibu solubility in presence of L-lactose, PI F127, HPMC, L-leucine and D-mannitol expected to contribute designing the phase diagram of ibu in aqueous ethanol solvent system for crystallization process.



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