

Mathematical representation of the stability of ibuprofen in binary and ternary solvent mixtures of PEG 200, ethanol and water at various temperatures

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Background and Aims: Stability test gives information about the storage conditions and shelf lives. Doing the forced degradation (stress testing) of a drug helps one to recognize the degradation products of it.

Methods: HPLC system with a modified method, mobile phase with the ratio of 60:40 from acetonitrile and water (adjusted to pH 1.81), flow rate of 1 ml/min and carbamazepine as the internal standard was used for determining stability factors of ibuprofen. The Jouyban –Acree model is used for fitting and predicting the stability factors at different temperatures:

where f_1 , f_2 , and f_3 are stability factors of ibuprofen in the solvent mixture, solvents 1,2 and 3. w_1 , w_2 , and w_3 are the mass fractions of the solvents 1,2 and 3. J , J' , J'' and J''' are model constants for binary and ternary interactions and T is temperature in Kelvin.

Results: The stability data of binary and ternary solvents were fitted to the jouyban-Acree model separately, the model constants were determined and the error values were 6.6% and 56.1%, respectively. The fitting error value of the binary and ternary mixtures was 19.0%. The obtained binary and ternary model constants were used for predicting the stability data points and the prediction error was 22.4%.

Conclusions: By producing a trained version of proposed model one can predict stability factors in different solvents compositions, therefore, it is possible to make a shortcut in the HPLC process and to select the special solvent mixtures with the desired stability of the drug.

Keywords: HPLC; Ibuprofen; Stability; Jouyban-Acree model