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Development and validation of an analytical method for Ibuprofen determination in matrix tablets by high performance liquid chromatography

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Background: The selection of a suitable analytical methodology is of fundamental interest for the quality control procedure of an active substance or dosage form. The tendency of the pharmaceutical industry has always been to produce medicines with quality, efficacy and safety, and such trend over the years has led to the development of recommendations and incorporation of requirements that have evolved to strict regulation, with the main objective to implementation of specific analytical techniques for identification and quantification of substances involved in the production of pharmaceutical dosage forms. Following control efforts developed under the quality control comes the concept of validation1. However, in general, the various existing concepts of validation reflect the same general direction, differing only as to how it had been previously observed by Chapman. The prominence given to the validation of analytical methods varies depending on the application area, the concentration of the analyte, the intention of the study and the nature of the method.

Purpose: The present study describes the analytical parameters that are aimed at achieving a valid alternative for ibuprofen (IBU) determination in matrix tablets. Chromatographic separation occurred reverse phase on a column of LiChroCART ® RP18 Purospher Star ® 250 mm length × 4.6 mm diameter in-suit and 5µm particle size (Merck, Darmstadt, Germany) coupled to a precolumn LiChro ® RP-18 (4 mm × 4 mm ID; average particle diameter of 5µm, Merck). The mobile phase used was a mixture of ACN: water: methanol: phosphoric acid - 58:37:5:0.05, v/v. The eluent was previously degassed under vacuum and filtered with a filter of porosity 0.45 micrometre (PVDF Tracer) and further degassed by sonication for 20 min. The chromatographic separation was performed isocratically with a flow rate of 1.5 ml / min and UV detection at 229 nm. Solution of Flurbiprofen (FN) was used as internal standard. The system isocratic was equilibrated one hour before testing with mobile phase at 25° C.

Methods: The chromatographic conditions were based by the proposed method by Shah and Jung. The validation parameters of the chromatographic method were analyzed: optimization of chromatographic conditions, selectivity, linearity, precision (repeatability and intermediate precision) and accuracy.

Results: The validation results showed that the time of separation, resolution and retention of the method was optimized by modifying the mobile phase at a flow rate to achieve a suitable resolution and FNP the drug in a short time for each analysis. The absorbance readings of the solutions containing excipients showed that the components of the formulations did not interfere with the method. The analysis by linear regression model, showed a correlation coefficient of 0.9999. The coefficients of variation were less than 2%, thus fulfilling internationally accepted criteria for the validation of analytical methods.

Conclusions: The results obtained have demonstrated that HPLC method and developed for quantification of IBU in the tablets feature parameters of selectivity, linearity and precision acceptable accuracy for the determination of this drug. Therefore, this methodology can be used at various stages of research and development of tablets and other dosage forms.

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