



Application of the Accuracy Profile to Validation of Chromatographic Method for Determination of Etoposide in Polymeric Matrix

Ana G. R. SOLANO ^{1,2} *, Gisele R. SILVA ¹ & Gérson A. PIANETTI ²

¹ *Campus Centro Oeste Dona Lindu, Federal University of São João Del Rei, Divinópolis, Minas Gerais, Brazil*

² *Department of pharmaceutical products, Faculty of Pharmacy, Federal University of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil*

SUMMARY. The validation of an analytical method should demonstrate that the method is suitable for its intended purpose. In the current study, the tolerance interval and accuracy profile, a statistical approach that allows defining a region where a predetermined proportion of future measurements obtained with the method will be observed, were applied to the validation of the chromatographic method for determination of etoposide incorporated into a polymeric implant. Hence, it was possible to define the range of etoposide concentrations to which the method may be applied (4.90 to 63.66 $\mu\text{g/mL}$), the quantitation limits (4.61 and 71.0 $\mu\text{g/mL}$), and the linearity of the analytical method. The accuracy profile showed to be a reliable and useful tool for the validation of chromatographic methods.

KEY WORDS: Accuracy profile, Etoposide, Polymeric implant, Tolerance interval, Validation.

* Author to whom correspondence should be addressed. *E. mail:* anagabriela@ufsj.edu.br