Stability Study of the Phytomedicine Gotas Arthur de Carvalho®


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Introduction: Gotas Arthur de Carvalho® (GAC) is a phytomedicine composed of three plant tinctures (Matricaria recutita, Genciana lutea and Foeniculum vulgare) with indications as digestive. Despite the GAC are in the pharmaceutical market since 1941, it does not have stability study, which is essential to predict and indicate the expiration date of pharmaceuticals. The aim of the present work was to evaluate stability of GAC based on the physical chemical assays including the analysis of principles actives/markers (apigenin-7-glucoside (APG), gentiopicroside (GTP) and trans-anethol (ANT) by HPLC.

Material and Methods: The stability study was conducted in climatic chamber at 40°C and 75% humidity during the period of 180 days (Brazil, 2005). The analysis of the GAC were realized in several times (0, 5, 10, 15, 20, 25, 30, 45, 60, 75, 90, 105, 120 130, 150, 165 180 days) with determination of the average volume, density and pH (F. Braz., 2010). In addition the content of the markers in the GAC was determined by RP-HPLC-DAD system (Alliance Waters 2695, USA) using an analytical method validated previously (LEAL et al., 2008).

Results and Discussion: The physical chemical analysis of the GAC did not detect significant changes in the average volume, density (0,9437 ± 0,30%) and pH (5,55 ± 1,43%) determined at different times until at the end of the study, 180 days. HPLC analysis of the GAC did not show considerable degradation of the principles actives/markers (APG, GTP and ANT). The residual percentage of APG and GTP of the samples was from 96 to 100 % after 180 days. Moreover, the level of ANT decreased during the study. This variation is possibly related to the chemical nature of this molecule sensitive to high temperature as 40 °C.

Conclusion: The GAC was stable during the study, however further studies are needed to determine in more detail the degree of stability of this herbal medicine.

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