PERFORMANCE EQUIVALENCE STABILITY TESTING OF TRADITIONAL MEDICINAL FORMULATIONS OF
Jiā Wèi Xiāo Yáo Săn /Wán
Augmented Rambling Power/pills
TRANSLATED NAME: 加味逍遥散(丸) /丹梔逍遙散 / 八味逍遙散

A Capstone Project

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ABSTRACT

Stability studies conducted on finished herbal medicinals are an important indication of product quality, purity, efficacy, and shelf life. This study focuses on three herbal medicinal vendors and their dose delivery systems of tablet, granule extract and tea pill of Jiā Wèi Xiāo Yáo Săn/Wán. The use of an analytical method known as reversed-phase high-performance liquid chromatography (RP-HPLC) has revealed the heat and humidity stability of each dosage form over time. Three dosage forms of Jiā Wèi Xiāo Yáo Săn/Wán from three vendors were subjected to dry heat (41° C) for 12 weeks and compared to control samples stored at 2-8° C. In a second arm of the experiment, samples were exposed to 70% humidity in a humidor for 12 weeks and compared to control samples stored at ambient humidity. After the 12-week incubation time, all samples were analyzed by RP-HPLC to determine degradation relative to controls. Results were tabulated and graphed to reflect degradation over time. Our primary goal was to determine the most stable, and therefore the most efficacious, dosage form of Jiā Wèi Xiāo Yáo Săn/Wán based on accelerated stability studies using the stresses of heat and moisture. Our secondary goal was to determine the greater factor contributing to sample erosion (heat or moisture) and to identify the vendor providing the most stable formulation under these conditions during short-term (1 week) and long-term (12 weeks) storage.