Determination of Dissolution Profile of Açaí in Simulated Fed and Fasted Intestinal States

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In recent years, there has been an increase in the use of botanical dietary supplements (BDS) along with other medications, specifically cancer treatments. Açaí (*Euterpe oleracea* Mart.) BDS is one such supplement that is seen to have health benefits, such as antioxidant and anti-inflammatory properties. Because BDS are not considered drugs by the Food and Drug Administration (FDA), dissolution profiles are not required and are less available in the literature. Therefore, the purpose of this research was to focus on determining the dissolution profile for two different formulations of açaí capsules. The Fed and Fasted State Simulated Intestinal Fluid (FeSSIF and FaSSIF), simulating physiological conditions of the GI tract, was used to evaluate two different açaí BDS.

For this experiment, the USP dissolution apparatus I (basket) was considered for the dissolution experiment. In order to measure the quality and accuracy of the possible data, the Performance Verification Test was performed using 10 mg prednisone tablets. These tablets were placed in the apparatus with filtered 37 °C water at a speed of 75 rpm for 30 minutes. This experiment was done twice, and the amount of drug released was measured and the absorbance using a UV spectrophotometer was measured. A calibration curve using seven different concentrations of prednisone powder was the reference standard. The geometric mean (GM) and percent coefficient of variation (%CV) calculated were 76.73 and 66.54% when the acceptance criteria were 47-76 and 15%, respectively. The GM was slightly greater than the range given, while the %CV was significantly larger. This shows a high variance between the cells of the apparatus which could be caused by low mechanical calibration. Because of the high variation in the instrument, a shaker was considered for the actual experiment. Shakers have been used for dissolution as well. The actual dissolution experiment was conducted similarly. Both formulations of açaí capsules were placed in the Fed and Fasted State simulated intestinal fluid media with a pH of 5 and 6.5 and set at the same speed and temperature. The mixtures were on the shaker for 24 hours before samples were taken and analyzed using Liquid ChromatographyMass Spectrometry (LC-MS). They were then cleaned with the different solid phase extraction (SPE) columns to try and find the best method for cleaning out the buffer salts and biomolecules that come from the media.

Fig. 1. Natrol and Nature's Way açaí capsules in the FeSSIF and FaSSIF after being on the shaker for 24 hours.

The samples were the cleanest with the HILIC Tips. Only the anthocyanin, peonidin glucoside, found in açaí was recovered. The chromatograms were still convoluted with proteins, peptides, and salts from the media. The next step for this experiment would be to optimize the cleaning step to better detect other constituents in the capsules. Subsequently, the solubility of the capsules at different intervals will be measured.

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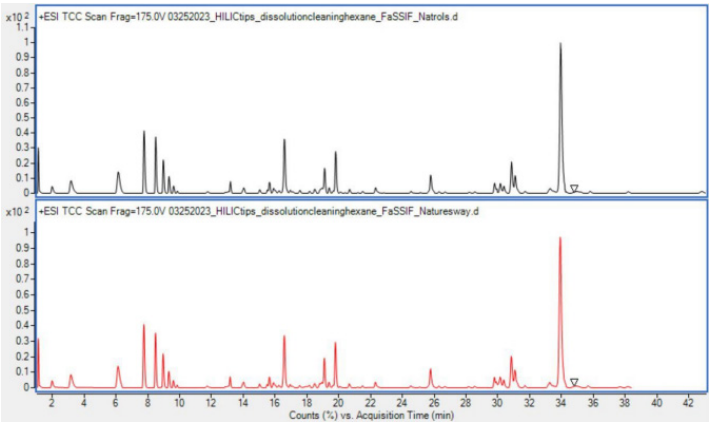

Fig. 2. The chromatograms of Natrol and Nature's Way açaí capsules in the FaSSIF media.

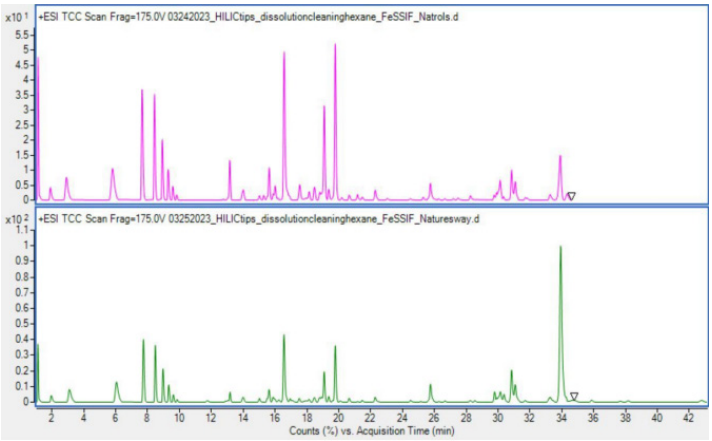

Fig. 3. The chromatograms of Natrol and Nature's Way açaí capsules in the FeSSIF media.

Statement of Research Advisor

Zalaya has contributed to developing an in vitro approach to determine what açaí constituents are dissolved in the gastrointestinal tract and further absorbed. This important approach will help to identify compounds that are responsible for botanical drug interactions.

-Angela I. Calderón, Department of Drug Discovery and Development, Harrison College of Pharmacy

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Authors Biography

Zalaya Haynes is a junior-year student pursuing a B.S. degree in Biomedical Sciences with a Minor in Africana Studies at Auburn University. She has played key research roles in researching and developing the protocol for the dissolution experiment. She plans to get into the Harrison College of Pharmacy's Pharm. D. program.

Zarna Raichura is a graduate student pursuing her Ph.D. in Medicinal Chemistry at Auburn University's Harrison College of Pharmacy. She got her bachelor's in pharmacy from Bhanuben Nanavati College of Pharmacy in Mumbai, India. Her research focuses on the possible inhibition of ashwagandha extract on CYP enzymes.

Angela Calderón is an associate professor at Auburn University's Harrison College of Pharmacy. She works in the Drug Discovery and Development Department and her current research deals with evaluating the potential of Ashwagandha extracts to produce CYP-mediated drug interactions and the mechanism of açaí BDS-anticancer drug interaction.