

## Overview

- High purity, full-spectrum extract of *Hibiscus sabdariffa*
- Specifically extracted from the calyx
- Complete traceability of the raw material
- Supports reduction in serum cholesterol
- Supports health blood pressure
- Clinically proven
- Water soluble
- Suitable for foods

## Results of Published Clinical Studies

### Blood Pressure

- Administering *Hibiscus sabdariffa* tea over four weeks to subjects having hypertension produced 11% reduction in systolic and 12% reduction in diastolic blood pressure.
- No significant difference was found between the effectiveness of the tea and the drug captopril.
- Doses of the tea adjusted to about 9.6 mg of anthocyanins proved optimally effective.
- Number of subjects per study ranged from 39 to 100.

### Cholesterol Reduction

Administering *Hibiscus sabdariffa* tea adjusted to 20 mg of anthocyanins reduced serum cholesterol 12% over four weeks. Forty-two subjects participated.

### Cardio HB Dosage

Based on the blood pressure and cholesterol reduction studies a 160 mg dose of Cardio HB 6% anthocyanins is recommended twice daily.

## Commonly Asked Questions

*How does the extract differ from the tea that was used in some of the clinical trials? Is the extract missing anything?*

All the active compounds mentioned in the studies are included in the extract. The extract contains the active ingredients in a more purified state free of simple sugars and other inactive ingredients found in the tea. These actives are present in a higher concentration, making it more suitable for dosage forms such as capsules or tablets.

*What is the recommended dosage?*

Based upon the clinical studies the dosage is 160 mg of the extract taken twice daily.

*What is a full-spectrum extract?*

The extract has all the active compounds such as anthocyanins, phenolic acids and other flavonoids found in the tea. It does not contain a highly purified single compound or a single class of compounds.

*What is the mechanism of action for each of the following and how does that relate to the extract?*

Cholesterol reduction: inhibits synthesis of triglycerides and reduces bad cholesterol formation

Blood pressure reduction: vasodilator, inhibits LDL oxidation, thereby reducing atherosclerosis; COX-2 inhibitor, reduces inflammation in the arteries

## Ensuring Heart and Cholesterol Claims: Testing The Extract

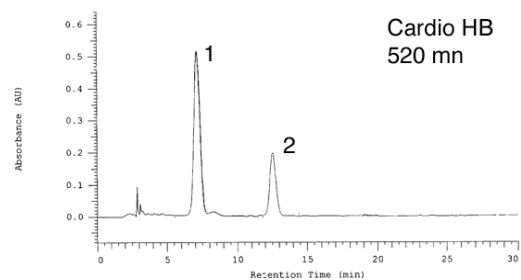
Cardio HB contains the same specific anthocyanins and phenolic acids as the *Hibiscus sabdariffa* itself thereby supporting researched claims. There are however, a number of low-cost extracts advertised to be from *H. sabdariffa* that do not produce a valid fingerprint, thereby placing the consumer and the marketer at risk. How to tell the difference?

High Pressure Liquid Chromatography (HPLC) analysis produces unique fingerprints of marker compounds. BioActives conducted a survey of extracts claiming to be from *H. sabdariffa*, subjecting each to an HPLC analysis comparing anthocyanin and phenolic acids standards specific to *H. sabdariffa*. Key to the fingerprint match is, among others, the presence of two major anthocyanin peaks Delphinidin sambubioside (1) and Cyanidin sambubioside (2). Clearly the Cardio HB sample contained both ingredients.

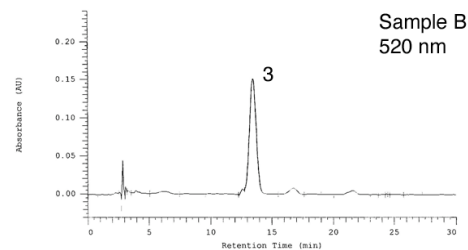
Other samples analyzed contained anthocyanins but not the ones responsible for the claims. Sample B for example, contained a single peak corresponding to Cyanidin glucoside (3). Other samples contained late eluting anthocyanins (4), such as in sample C. Some samples contained the proper anthocyanins but upon quantitative analysis had much lower levels than claimed.

Finally, an additional HPLC for phenolic acids showed that Cardio HB has the same phenolic acid profile as authentic *H. sabdariffa*. Sample B had a very different phenolic acid profile while Sample D showed traces of phenolic acids not present in *H. sabdariffa*.

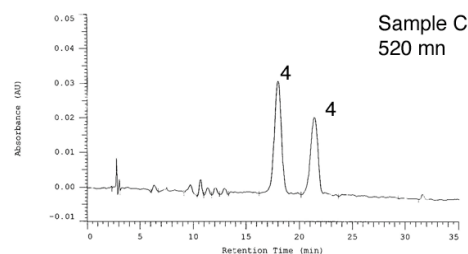
Conclusion: Cardio HB has the *H. sabdariffa* fingerprint others may not.



Cardio HB shows major peaks for anthocyanins 1 & 2 consistent with *Hibiscus sabdariffa* anthocyanins fingerprint



Sample B shows an anthocyanin that is not consistent with the *Hibiscus sabdariffa* fingerprint



Sample C shows two late eluting anthocyanins again not consistent with the *Hibiscus sabdariffa* fingerprint

## Bibliography

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2. Herrera-Arellano A et. al. Clinical effects produced by a standardized herbal medicinal product of *Hibiscus Sabdariffa* on patients with hypertension. A randomized, double-blind, Lisinopril-controlled clinical trial, *Planta Med* 2007; 73; 6-12
3. Herrera-Arellano A., Effectiveness and tolerability of a standardized extract from *Hibiscus sabdariffa* in patients with mild to moderate hypertension: a controlled and randomized clinical trial, *Phytotherapy* 11 (2004) 375–382
4. McKay, D.L., Saltzman, E., Chen, C., Blumberg, J. 2008. *Hibiscus sabdariffa* L. Tea (Tisane) Lowers Blood Pressure in Prehypertensive and Mildly Hypertensive Adults. *Circulation*. 118:S-1123.
5. Tzu-Li Lin, *Hibiscus sabdariffa* extract reduces serum cholesterol in men and women, *Nutrition Research* 27 (2007) 140– 145

## About BioActives

BioActives produces value-added highly water-soluble and highly bioavailable lipophilic active ingredients using its patented processes. The company's line of MicroActive<sup>®</sup> ingredients demonstrate superior bioavailability in uptake amount and consistency thereby reducing inter-subject variance. MicroActive<sup>®</sup> ingredients assure consumers maximum efficacy regardless of diet, health condition or risk factors - they are cost-effective and easily formulated. Combining its U.S. based research facility with its G.M.P. production facility in India, the company is able to commercialize its research bringing a steady stream of value-added and MicroActive<sup>®</sup> products to the market. BioActives' corporate headquarters and research facility are located in Worcester, MA.

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## BioActives LLC: Cardio HB™ Product Specification

**Botanical Source:** Hibiscus Sabdariffa

**Plant Part Used:** Calyx

**Country of Origin:** Thailand/processed in India

**Appearance:** Powder

**Color:** Dark purple

**Excipient:** Maltodextrin

**Solubility:** Water, 20% methanol or ethanol

**HPLC Identification:** Delphinidin sambubioside (major peak) cyanidin sambubioside (minor peak)

**Assay:**

Anthocyanins (UV/Vis, as Delphinidin sambubioside): Not less than 6%

Total Phenolics (Folin Ciocalteu, as Catechin): Not less than 15%

**Loss on Drying:** Not more than 10%

**Heavy Metals (USP, Method II):** Not more than 10ppm

**Pesticide Residues:** None detected

**Microbiological Profile:**

Total Plate Count: Less than 1000cfu/g

Yeast and Mold: Less than 100cfu/g

*E. coli*: Negative

*Salmonella* sps: Negative

*Staphylococcus aureus*: Negative

*Pseudomonas aeruginosa*: Negative

**Shelf-life:** Two years from the date of manufacture when stored unopened protected from light and moisture.

**Storage:** Protected from light, store in a cool dry place, preferably refrigerated

### HPLC Profile

