



UNIVERSIDAD DE GUAYAQUIL
DEPARTMENT OF CHEMICAL SCIENCES

Ciudadela Universitaria "Dr. Salvador Allende"
Telephone: 2293680, E-mail: fcquimic@ug.edu.ec

Guayaquil, Ecuador

FINAL REPORT

CODE: 04/06

TITLE:

Comparing the anti-inflammatory effects of the products known as **Tahitian NONI**, originating from Morinda Laboratories INC, Utah, United States and **NONI Juice Concentrate**, originating from NutraMedix Laboratories, LLC, Florida, United States.

OBJECTIVES:

To compare the anti-inflammatory effects of **Tahitian NONI** and **NONI Juice Concentrate**, using a topical application; measured by auricular edemas in laboratory mice.

BACKGROUND:

The auricular edema method is based on applying 12-O- Tetradecanoil Forbol-13 Acetate (TPA), one of the components responsible for the irritating action of croton oil, into the auditory pavilion of the mouse. The inflammatory reaction consists of erythema, edema and infiltration by polymorph nuclear leukocytes. As such, eicosanoid-type mediators are freed, inducing degranulation of the mast cell. This technique thus allows the evaluation of the inhibiting substances of the biosynthesis of prostaglandins and leukotrienes.

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As discussed in numerous international works, the pharmacological study of the above-mentioned effect is indispensable, and guarantees, within the margin of error associated with the technique, that the potential for producing anti-inflammatory effects in humans will be learned.

The basis of this work is the pharmacological effect as an anti-inflammatory, as described in international literature (1, 2).

VARIABLES TO MEASURE:

1. Weight of the treated and untreated ears
2. Percentage of Inflammation
3. Percentage of Inhibition

PROCEDURES TO FOLLOW:

TEST MATERIALS:

For the evaluation of **Tahitian NONI** and **Noni Juice Concentrate** the procedure described by CYTED (1996) and the Gerhard Voegel (1997) was followed.

CHANGES IN THE CURRICULUM:

Changes did not take place in protocol proposed to the Unity of Quality Guarantee, whose number is referred to on Page 1.

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DATA FROM THE SAMPLE:

For the Noni Juice Concentrate:

Organization soliciting services: NutraMedix Laboratories, LLC.

Person in charge of the Organization's application: Eng. José Icaza

Date of application: 4/20/05

Person in charge in the Executor Organization: MSc. Gastón Garcia Simón.

Storage: The product was maintained at room temperature before and during the experiment, and as indicated was protected from light and kept in a locked cabinet.

Organization that carried out the work: University of Guayaquil, Department of Chemical Sciences.

Address: Ciudadela Universitaria "Dr. Salvador Allende"

Form of presentation of the product: Amber glass drop bottle containing 30 milliliters.

For the Tahitian Noni:

Organization soliciting services: Morinda Inc, Utah, United States.

Person in charge of the Organization's application: Eng. José Icaza

Date of application: 5/31/05

Person in charge in the Executor Organization: MSc. Gastón Garcia Simón.

Storage: The product was refrigerated as indicated, and protected from light.

Organization that carried out the work: University of Guayaquil, Department of Chemical Sciences.

Address: Ciudadela Universitaria "Dr. Salvador Allende"

Form of presentation of the product: Amber glass bottle containing 1 liter.

INFORMATION WITH RESPECT TO THE HANDLING:

No special handling instructions were needed.

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COMPOSITION OF THE PRODUCT:

Tahitian Noni: It is NOT made of dehydrated or powdered *Morinda citrifolia*

Fruit juice of the *Morinda Citrifolia* plant

Natural grape juice

Bilberry Juice

Natural flavors

Noni Juice Concentrate

Noni extract

Mineral water

Ethanol

EXPERIMENTAL PROCEDURE:

INTRODUCTION:

This experiment was carried out with the intention of comparing the anti-inflammatory effects of Tahitian NONI and Noni Juice Concentrate, utilizing croton oil as the inflammatory agent.

DOSAGE USED IN THE TEST:

This test was conducted by applying 50 μL of the products that are the object of this study divided between both faces of the auditory pavilion.

PRINCIPAL TEST:

METHODS AND TECHNIQUES:

Study Material: Tahitian Noni and Noni Juice Concentrate.

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Animal Model: A single rodent species (mouse) was utilized, with a minimum of 5 animals of a single sex in each group. In this case male mice with an average weight within $\pm 20\%$ (3), belonging to the Swiss line and coming from the Chemistry Department of the University of Guayaquil were appropriate and were utilized in the experiment.

The animals were maintained in quarantine conditions and were acclimated according to established procedures (4, 5), said period having a duration of five days minimum.

Access to the water and the food was "ad libitum" (6, 7).

The animals were randomly distributed from within the different groups. (8)

Food was denied 4 hours before exposure to the test material.

The experiment lasted 6 days (5 of acclimation and 1 of test).

DEVELOPMENT OF THE METHOD:

Three groups were created for each test – 6 in total – which can be viewed in the following tables:

TEST GROUPS FOR THE TAHITIAN NONI TEST	
1	Flebogenous Agent (oil of croton 20 μ L)
2	Flebogenous Agent (oil of croton 20 μ L) + Feldene covering the two sides of the auditory pavilion.
3	Oil of croton 20 μ L + 50 μ L of Tahitian Noni

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TEST GROUPS FOR THE NONI JUICE CONCENTRATE TEST	
1	Flebogenous Agent (oil of croton 20μL)
2	Flebogenous Agent (oil of croton 20μL) + Feldene covering the two sides of the auditory pavilion.
3	Oil of croton 20μL + 50μL of Noni Juice Concentrate

The mice were denied food for hours then weighed, after which began the experiment. After the fasting all animals were weighed to determine the appropriate dosage.

The irritant solution of 5% croton oil in acetone was applied topically in the right ear, at the indicated volume, using an automatic pipette.

The composite solutions were administered topically in the right ear immediately after the irritant, in the indicated volume.

30 minutes after the application of the irritant, the animals are euthanized in a saturated ether atmosphere, and their ears are cut along the edge. 6 mm discs were cut with a punch then weighed.

RESULTS CALCULATIONS:

Outcomes are rated by calculating the weight of each mouse's ears, both the treated and untreated.

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The percentage of inflammation of the treated as opposed to the untreated ear is calculated using the following formula:

$$\text{Percentage of Inflammation} = \frac{T \times 100}{ST} - 100$$

Where T is the average of the weights of the treated ears (right) and ST is the average of the weights of the untreated ears (left).

$$\text{Percentage of Inhibition of inflammation} = \frac{C - T}{C} \times 100$$

Where C is the average value of % of inflammation of the animals of the control group and T is the average value of % of inflammation of the animals of the experimental group (either Croton and Feldene or Croton and Noni).

DESCRIPTION OF THE DOSAGE, METHOD OF ADMINISTRATION AND DURATION OF THE TEST:

The test was achieved by following the method established by CYTED and using the dose of 50µL each mouse.

The composite solutions were applied in the right auditory pavilion of the study animals, the left auditory pavilion being the control.

20 µL of the flebogenuous agent was utilized.

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ANALITICAL RESULTS:

The results of the average value of the weights of the right and left ears are found in Tables 1 and 2:

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TABLE # 1. STUDY OF THE ANTI-INFLAMMATORY EFFECT OF TAHITIAN NONI (weight of ears in mg)		
Group	Right Ear	Left Ear
Control Group Treated with Oil of Croton		
Mean ± s.d.	16.86 ± 1.56	8.72 ± 0.567
Croton + Feldene		
Mean ± s.d.	9.28 ± 0.3	9.26 ± 0.7
Croton + Tahitian Noni		
Mean ± s.d.	15.1 ± 2.53	9.20 ± 1.36



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**TABLE # 2. STUDY OF THE ANTI-INFLAMMATORY EFFECT OF NONI JUICE
CONCENTRATE
(weight of ears in mg)**

Group	Right Ear	Left Ear
Control Group Treated with Oil of Croton		
Mean ± s.d.	13.4 ± 2.3	6.2 ± 3.3
Croton + Feldene		
Mean ± s.d.	9.38 ± 0.3	9.36 ± 0.7
Croton + Noni Juice Concentrate		
Mean ± s.d.	8.48 ± 0.77	8.42 ± 0.8

From the values in Tables 1 and 2, the percentages of inflammation and inhibition are calculated. The results are in Table 3.



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**TABLE # 3. STUDY OF THE ANTI-INFLAMMATORY EFFECT OF TAHITIAN NONI
AND NONI JUICE CONCENTRATE**

PERCENTAGE OF INHIBITION AND INFLAMMATION

Group	% Inflammation	% Inhibition
Croton	93.3	-
Croton + Feldene	1.0	99.1
Croton + Tahitian Noni	64.78	33
Croton	116.12	-
Croton + Feldene	0.21	99.7
Croton + Noni Juice Concentrate	0.71	99.38

The table demonstrates that the anti-inflammatory and analgesic agent Feldene at the 0.5% level (Piroxicam) showed a marked anti-inflammatory effect, similar in both tests, with very small variations. Similarly croton, used to produce inflammation in the animals' auditory pavilions, showed little variation in the two tests. On the other hand, Tahitian Noni, one of the study products, although possessing an anti-inflammatory effect it was less than Feldene. In addition, the percentage of inhibition was less than the aforementioned medication, in the model that utilizes croton oil, which is habitually used to produce acute inflammation in experimental models.

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On the other hand Noni Juice Concentrate produced a marked topical anti-inflammatory effect which was superior to Tahitian Noni and very similar to Feldene, used in our study as the positive control.

CONCLUSIONS:

1. **Tahitian NONI** demonstrated to have an anti-inflammatory effect but to a lesser extent than **Noni Juice Concentrate** and less also than Feldene.

2. Feldene was also shown to have the effect for which it is sold.

GENERAL CONCLUSIONS:

Tahitian NONI has demonstrated to have anti-inflammatory effect in tests using mice as subjects, and as appears in specialized literature, but to a lesser extent than **Noni Juice Concentrate**, which produced a marked anti-inflammatory action.

PERSONNEL RESPONSIBLE FOR THE STUDY: SIGNATURE

Responsible Professional:

MSc. Gastón García Simón.

Signature:



Date: 05/10/05

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