UNIVERSIDAD DE GUAYAQUIL
DEPARTMENT OF CHEMICAL SCIENCES

Ciudadela Universitaria ¨Dr. Salvador Allende¨

Telephone: 2293680, E-mail: fcquimic@ug.edu.ec

Guayaquil, Ecuador

REPORTE FINAL

CODE: 38/05

TITLE:
Establishment of the potential analgesic effect of the product known as **Cumanda,** originating from NutraMedix Laboratories, LLC, Florida

OBJECTIVES:
To study the possible analgesic effect of **Cumanda**, measured by stretching and writhing in laboratory mice.

BACKGROUND:
A substance's analgesic activity may be measured by antinociceptive tests, based in the application of painful (analgesic) stimuli and the appearance of typical, observable changes in the conduct of the animal. It can not be assumed necessarily that animals have the same sensations of pain as human beings.

The majority of study methods are based on the application of the problem and the determination of the pain threshold that said application provokes upon subjecting the animal to nociceptive stimuli of known intensity and conditions. Such stimuli may be mechanical, thermal, electric, or chemical.

The present study has as background the possible analgesic effect of Cumanda.

REPORTE FINAL

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 analgesic effects in humans will be learned.

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

TECHNICAL, SCIENTIFIC AND SOCIOECONOMIC BENEFITS:
The demonstration of this product as an analgesic is important due to its potential as a new, plant-based medication, with its associated low toxicity. This was demonstrated by us in a previous work, allowing us to enter the product as a new medication in the appropriate Register.

VARIABLES TO MEASURE:
1. Number of times animal writhes.
2. Number of stretches, both in twenty minutes.
3. % of analgesia.

PROCEDURES TO FOLLOW:

TEST MATERIALS:
Cumanda: the procedure followed was that described by CYTED (1996) and the Gerhard Voegel (1997).

UNIVERSIDAD DE GUAYAQUIL
DEPARTMENT OF CHEMICAL SCIENCES

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

REPORTE FINAL

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**.**

DATA FROM THE SAMPLE:
Organization soliciting services: NutraMedix Laboratories, LLC.
Person in charge of the Organization's application: Jose Icaza
Date of application: 4/20/05
Person in charge in the Executor Organization: MSc. Gastón Garcia Simón.
Storage: The product was stored at room temperature with controlled access.
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
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.

INFORMATION WITH RESPECT TO THE HANDLING:
No special handling instructions were needed.

COMPOSITION OF THE PRODUCT:
Cumanda bark extract
Mineral water
Ethanol (20 – 25%)

UNIVERSIDAD DE GUAYAQUIL
DEPARTMENT OF CHEMICAL SCIENCES
Ciudadela Universitaria ¨Dr. Salvador Allende¨
Telephone: 2293680, E-mail: fcquimic@ug.edu.ec
Guayaquil, Ecuador

REPORTE FINAL

EXPERIMENTAL PROCEDURE:

INTRODUCTION:

This experiment was carried out with the intention of determining the possible analgesic effect of CUMANDA, using it orally, given that this is the proposed method of use in humans.

DOSAGE USED IN THE TEST:

0.5 ml of Cumanda per 20 g of animal's body weight.

PRINCIPAL TEST:

METHODS AND TECHNIQUES:

Study Material: **Cumanda**

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 ± 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:
The following three groups were constructed for the test:

TEST GROUPS	
1	**Analgesic agent (acetic acid at 3%)**
2	**Aspirin (200 mg/kg) + Acetic Acid at 3%**
3	**Cumanda (25 mL/kg) + Acetic Acid at 3%**

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

The extract, the referred substance, was administered orally in a volume of 0.5 mL, 1 hour before the intraperitoneal injection of 0.25 mL of a liquid solution of 3% acetic acid. The proprietary drug is salicylic acetic acid in a dose of 200 mg/kg.

Each animal is isolated in an individual box immediately following the administration of the analgesic agent. It is then observed for the number of writhing and stretches during the next 20 minutes.

RESULTS CALCULATIONS:
The arithmetic mean of each group, along with the corresponding error is used to determine the percentage of analgesia. For this percentage, the difference between the number of writhing of the group receiving just acetic acid (value 100) and that of the group receiving intervention is calculated.

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 0.5 mL/20g each mouse.

Oral administration was used for the testing and the reference materials, using an intragastric canula. The analgesic was administered intravenously.

ANALITICAL RESULTS:
The results of the number of writhing and stretches are found in Table #1.

UNIVERSIDAD DE GUAYAQUIL
DEPARTMENT OF CHEMICAL SCIENCES

TABLE # 1. STUDY OF THE POSSIBLE ANALGESIC EFFECT OF CUMANDA

Group	Animal	Writhing	Stretching
Analgesic Agent	1	13	1
	2	3	2
	3	7	10
	4	13	3
	5	8	2
Total		**44**	**18**
Mean ± s.d.		**8.8 ± 4.2**	**3.6 ± 3.6**
SAA + Analgesic Agent	1	0	0
	2	1	0
	3	3	0
	4	0	0
	5	0	0
Total		**4**	**0**
Mean ± s.d.		**0.8 ± 1.3**	**0 ± 0**
Cumanda + Analgesic Agent	1	1	0
	2	7	0
	3	3	0
	4	3	0
	5	0	0
Total		**14**	**0**
Mean ± s.d.		**2.8 ± 2.6**	**0 ± 0**

UNIVERSIDAD DE GUAYAQUIL
DEPARTMENT OF CHEMICAL SCIENCES

Ciudadela Universitaria ¨Dr. Salvador Allende¨

Telephone: 2293680, E-mail: fcquimic@ug.edu.ec

Guayaquil, Ecuador

REPORTE FINAL

As can be seen in the table, the number of writhing and stretches counted in the proprietary drug group, as well as in the substance under study, were less than that of the analgesic group. When the percentage of analgesia is calculated, our product produces 86%, which indicates its analgesic effect.

CONCLUSIONS:

1- Cumanda was demonstrated to have an analgesic effect as assumed in the objectives of the trial.

2- Aspirin showed the greatest results.

GENERAL CONCLUSIONS:

Cumanda was demonstrated to have an analgesic effect in the study using mice, as appears in specialized literature.

PERSONNEL RESPONSIBLE FOR THE STUDY:

Responsible Professional: **Signature:**

MSc. Gastón García Simón

Date: 05/03/05

BIBLIOGRAPHY:

1. CYTED course for Researchers in the Discovery of new medicines, Lima November 1996, Edema Earpiece pp 83.
2. Drugs Discovery, Gerhard Voegel (1997).
3. Procedure. Bodily weight of mice
4. Procedure. Guide for the care of laboratory animals
5. Procedure. Quarantine
6. Procedure. Sub-minister of Water, Usage Manual.
7. Procedure. Random Allocation of rodent species
8. Procedure. Euthanasia
9. Pink W. “Statistics for toxicology,” in *Principles and methods of Toxicology*, W. Hayes, ed. Raven Press, N:Y: 1994