



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: 25/05

TITLE:

Establishment of the potential sedative effect of the product known as **Babuna Sleep**, originating from Nutramedix Laboratories, LLC. Florida, United States.

OBJECTIVES:

To study the possible effectiveness of Babuna Sleep in producing effects on the central nervous system in laboratory rats, following techniques described in the literature.

BACKGROUND:

Tests described in the literature and those that we have carried out have as a goal the determination of a medication's effect on the central nervous system. These effects are not limited to sedation, hypnotic, and tranquilizing, but also anti-depressive, which in high doses is known to prolong sleep induced by hexobarbital or other barbiturates.

The loss of the rightening reflex is measured as the criteria of the duration of the sleep that is induced by the barbiturates. In this test mice are used since metabolic elimination is rapid in this species.

The present study has as background the possible sedative effect of Babuna Sleep.

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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 sedative effects in humans will be learned.

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

TECHNICAL, SCIENTIFIC AND SOCIOECONOMIC BENEFITS:

The demonstration of this product has a sedative effect 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:

Determination of sleep time, comparing sodium pentothal and diazepam (rightening reflex).

PROCEDURES TO FOLLOW:

TEST MATERIALS:

Babuna Sleep. The procedure followed was that described by CYTED (1996) and the Gerhard Voegel (1997).

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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 García Simón.

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:

Chamomile Flower extract

Mineral water

Ethanol (20-25%)

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EXPERIMENTAL PROCEDURE:

INTRODUCTION:

This experiment was carried out with the intention of determining the possible sedative effect of Babuna Sleep using oral intake, given that this is the manner in which humans will use the product.

DOSAGE USED IN THE TEST:

This study utilized 0.4 ml/20 g of animal weight.

PRINCIPAL TEST:

METHODS AND TECHNIQUES:

Study Material: Babuna Sleep

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)

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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	Sodium pentothal dose of 48 mg/kg in a volume de 0.4 ml/20 g of mouse body weight (via intraperitoneal)
2	Sodium pentothal (in equal volume and dosage as the control group) via i.p. + diazepam 2.5 mg/kg (0.5 ml/20g of body weight, orally
3	Sodium pentothal 48 mg/kg (in equal volume and dosage as the control group) via i.p. + Babuna Sleep 0.4 ml/20 g of body weight, orally

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

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Three groups of five mice were formed, each mouse weighing an average of 30 grams. Each mouse received a dose (2.5 mg per kg of weight) orally, with the respective compound, that is, Diazepam, or the product which is the object of this study, in this case Babuna Sleep.

30 minutes later the selected barbiturate was administered via intraperitoneal, in this case sodium pentothal, in the dosage described above.

The animals were placed on their backs and covered with a blanket to maintain an acceptable temperature. The time to return to the righthening reflex was then measured, starting with the time of the administration of Pentothal.

If any doubt existed as to the return of the righthening reflex, the technique allowed the animal to be placed again on its back to see if it righted itself within one minute.

STATISTICAL PROCESS:

Mean times and standard deviations were obtained for each group and then contrasted statistically using one-way ANOVA with the posterior application of the Student Newman Keuls test ($p > 0.05$).

At the end of the experiment all the mice were euthanized according to procedures of Refinement to avoid suffering.

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

2.5 mg/kg of Diazepam was administered, and 0.4 ml/20 g of body weight of the Babuna Sleep product. Both were administered orally while the sodium pentothal was administered via intraperitoneal at a dosage of 48 mg/kg.

The test lasted six days.

ANALITICAL RESULTS:

The average value and standard deviation of sleep of each group, and whether the differences are statistically significant ($p < 0.05$) is found in Table #1.

TABLE # 1. SLEEP TIME IN MINUTES (Mean and Standard Deviation)		
Groups	$\bar{X} \pm s.d.$	Statistical Significance
Sodium Pentothal	49 \pm 4.32	a
Diazepam + Pentothal	119.6 \pm 4.3	b
Babuna Sleep + Pentothal	129.8 \pm 8.73	b

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As can be discerned from the above table, the greatest values for recovering the righthening reflex were obtained by the Diazepam and the Babuna Sleep, and were greater than the animals treated only with sodium pentothal (different letters).

Statistical analysis showed that the groups treated with Diazepam and Babuna Sleep differed significantly from the group treated only with sodium pentothal.

CONCLUSIONS:

From the evaluation of the sedative effect of **Babuna-Sleep** present model, one can assert that the product accomplishes the pharmacological effect that is attributed to it.

PERSONNEL RESPONSIBLE FOR THE STUDY:

Responsible Professional:
MSc. Gastón García Simón.

Date: 08/05/05

Signature:



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