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Evaluation of Acute Toxicity of Hydro-Ethanolic Extract of *Tricholepis glaberrima*

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ABSTRACT

***Tricholepis glaberrima* is used to treat skin conditions and male infertility. The aim of the research was to evaluate whether the hydro-ethanolic extract of aerial parts of *Tricholepis glaberrima* could cause acute oral toxicity in swiss albino mice and how it affected their behavior. The acute toxicity trials were conducted according to OECD guidelines 423, with a single oral dosage and a 14-day follow-up. After 24 hours, body weight, food and water consumption, signs of toxicity, and mortality were reported. Up to a dosage of 2000 mg/kg, oral administration resulted in no treatment-related mortality in animals. In the acute toxicity study, the hydro-ethanolic extract of aerial parts of *Tricholepis glaberrima* had an LD_{50} of greater than 2000 mg/kg, indicating that extract from this plant is acceptable for use in conventional medicine.**

Keywords: Impotence; OECD 423; body weight; toxicity; mortality.

1. INTRODUCTION

The bond between plants and humans is as ancient as humanity itself, dating back to the dawn of history. Recently, there has been a change in the general trend of drug selection from engineered to homegrown medications, which we may call 'Moving Back to Nature'.[1] Restorative plants have been recognized for decades and are commonly accepted as a rich source of remedial agents for the prevention of diseases and disorders all over the globe. The WHO (World Health Organization) has recently described traditional medicine (including home-grown medications) as interve-ntional treatment that has existed for many years before the incidents that led to the spread of modern medication, which is still in use today. Herbalism, also known as "Natural Medicine" or "Medicinal Botany," is a traditional healing or people's discipline centered on the use of plants and plant extracts.[2]

Animal toxicity research is done on novel drugs to determine possible health risks before they are given to humans. Toxicity testing entails a variety of experiments in several animals, as well as ongoing screening for clinical and biochemical anomalies that may occur during long-term drug administration.[3,4] The primary goal of our research was to assess the toxicity of a hydro-ethanolic extract of *Tricholepis glaberrima* before it could be used in public-health applications.

Tricholepis glaberrima, a member of the Asteraceae family, is used to treat skin disorders &

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infertility. This plant's aerial parts are used as a nervine tonic. The spice is thought to have antibacterial effects. It is indicated for debility and impotence in the early stages.[5] Flavonoids, sterols, triterpenoids, and glycosides are present in *Tricholepis glaberrima*. Cyanapicrin, guaianolides, betulin, stigmasterol, spinasterol, stigma-7-enol, cycloart-23-en-3-beta, and 25-diol are among the bioactive compounds present in it. Trichotetrol, cyclotrichosantol, cycloeucalenol, and quercetin-3-rutinoside are also reported.[6] It has aphrodisiac effects and is used to treat leucoderma, neurological conditions, hepatic disorders, and skin diseases. Its infusion has been used to treat impotence and seminal debility.[6,7] As a result, the acute toxicity profile of hydro-ethanolic extract of *Tricholepis glaberrima* was investigated in swiss albino mice, with a focus on behavioral aspects.

2. MATERIAL AND METHODS

2.1 Collection and Preparation of Plant Extract

Dr. K. Madhava Chetty, Plant Taxonomist, Asst. Professor, Department of Botany, Sri Venkateswara University, Tirupathi, India has authenticated the aerial parts of *Tricholepis glaberrima* collected from Chittoor District (Receipt: 0985). For ten days, the aerial portions of *Tricholepis glaberrima* were allowed to air dry. After that, the aerial parts were ground up into a gritty powder. 300 g of aerial parts (1:1) subjected to maceration process using ethanol and water in 7:3 ratios obtaining hydro-ethanolic extract of *Tricholepis glaberrima* (HETG).[9]

2.2 Experimental Animals

The experimental protocol was approved by Institutional Animal Ethics Committee, Central Animal House (Protocol No.: 1864/PO/Re/s/16 /CPCSEA), Shadan Institute of Medical Sciences, Hyderabad, India. Albino female wistar mice weighing between 25-30 g were used. The animals were maintained under standard laboratory conditions, 12-hr light/ dark cycle under controlled temperature. The relative humidity of the rooms was maintained at 70 ± 5 %. Mouse cages made of polyurethane were used to shelter the animals. The animals were given rice husk bedding and the cages were washed on a regular basis. Before the experiment, mice were allowed a normal diet pellet and free access to water and were accustomed to the experimental atmosphere for at least one week prior to study period.

2.3 Acute Toxicity Study

The acute toxicity study was carried out in female rats in a stepwise procedure with three animals per stage, as suggested in the OECD 423 guideline for acute oral toxicity class method. The animals were fasted overnight and given only water before receiving plant extract through oral gavage, beginning at 300 mg/kg and increasing the dose relying on the response. For the first 4 hours, the animals were carefully watched for any symptoms of toxicity, such as increased muscle function, salivation, convulsions, coma, and death. Over the next 24 hours, observations were made at daily intervals. The rats were monitored for another 14 days, and the number of rats that died during the study period was reported. According to the guideline theorem, the lethal dose in 50% (LD_{50}) was calculated.[9,10]

3. RESULTS

During the research phase, the experimental animals were in good condition and receptive to the drug being tested. A total of six animals were used in the acute toxicity trial, which lasted 14 days.

3.1 Effect on Body Weight

Almost all of the animals in the treated groups did not exhibit any substantial reduction in body weight over the course of 14 days as contrasted to the 0 day values, showing that there were no signs of toxicity. The data is given in Table 1.

3.2 Effect on Food and Water Consumption

For all dosage ranges, the research animals' food and water consumption did not improve significantly. Tables 1 provide the data for food and water intake, respectively. When comparison to the the day 0, at the end of 14 days of general observation, physical appearance such as eye color, mucus membrane, salivation, discharge, fur color, lethargy, and restlessness showed no improvement.

Table 1: Effect of HETG on body weight, food and water intake

Day	Body Weight (gm)		Food Intake (gm)		Water Intake (cm^3)	
	300 mg/kg	2000 mg/kg	300 mg/kg	2000 mg/kg	300 mg/kg	2000 mg/kg
0	27.2	26.9	24	26	22	20
1	26.0	26.2	22	24	23	21
2	26.4	26.1	24	27	21	20
3	27.6	27.7	22	23	22	20
4	26.7	26.6	20	23	23	19
5	26.4	26.5	24	25	17	20
6	27.2	27.0	24	24	23	22
7	27.1	27.5	24	26	23	23
8	26.8	26.5	21	22	22	20
9	26.3	26.5	22	24	21	19
10	26.5	26.7	20	23	22	20
11	25.8	25.7	24	25	19	21
12	26.4	26.3	26	25	20	21
13	26.3	26.7	25	25	22	20
14	26.3	26.5	22	23	23	20

Table 2: Effect of HETG on behavior, neurological and autonomic response

Behavioral Response		Neurological Response		Autonomic Response	
Alertness	D	Righting response	N	Writhing	I
Stereotypy	N	Limb tone	N	Defecation	I
Irritability	I	Grip strength	I	Urination	I
Fearfulness	I	Twitching	N	Piloerection	I
Touch response	I	Abdominal tone	I	Salivation	N
Analgesia	I	Pinnal reflex	N	Respiration	N
Spontaneous activity	I	Corneal reflex	N	Pupil size	N
Grooming	I	Straub tail	I	Cyanosis	N
Restlessness	N	Tremors	N	Heart rate	N
Inclined plane test	N	Convulsions	N	Lachrymation	N
Body Temperature	N	Catalepsy	N	Ptosis	N

N= Normal, I = Increases, D = Decreases.

3.3 Behavioral, Neurological and Autonomic Profile

Table 2 demonstrates the effects of improvements in the general mental, physiological, and autonomic profiles.

3.4 Mortality

The key criterion for deciding acute toxicity (LD_{50}) of any medication is mortality. At the maximum dosage level, 2000 mg/kg body weight, no mortality was observed. There was no mortality recorded even at the highest dose level i.e., 2000 mg/kg body weight.

4. DISCUSSION

This was the first systematic research into the safety of hydro-ethanolic extract of *Tricholepis glaberrima*. It was discovered that the LD_{50} of *Tricholepis glaberrima* hydro-ethanolic extract may be greater than 2000 mg/kg, placing the plant in GHS Category 5.

Body weight is a significant indicator of an animal's health. The onset of an adverse reaction is often preceded by a loss of body weight. A toxic dosage is the one that induces a 10% or greater decrease in body weight. It is described as the dosage that has the least toxic effect, regardless of whether or not it is followed by other changes. In the present study, the difference in rank average body weight during the treatment time was statistically non-significant, and 2000 mg/kg appeared to be treatment dependent, as higher dose treated groups did not display a reduction in body weight.

Food intake remained constant during the study. There was no difference in food intake levels among all classes as time passed (in days). The results of the acute toxicity showed that the hydro-ethanolic extract of *Tricholepis glaberrima* was tolerable up to the prescribed maximum dose (2000 mg/kg). Food intake may remain stable, but weight gain may be hampered by experimental stress, such as the use of oral gavage and/or handling disruptions.[11] When pretreatment values vary from post-treatment values in control animals, it's natural to make changes to handling or research procedures.

Up to a dosage of 2000 mg/kg, oral administration of a hydro-ethanolic extract of *Tricholepis glaberrima* revealed no treatment related mortality and no substantial treatment related morbidity. However, piloerection, muscle twinge, and lethargy were found shortly after the 2000 mg/kg administration, and they disappeared within an hour. Toxic symptoms differ depending on the species, but they can easily be extrapolated to humans. As a result, the current research may act as a building step for a human toxicity study.

5. CONCLUSION

From the present acute toxicity studies, hydro-ethanolic extract of *Tricholepis glaberrima* can be graded as Level 5 according to the GHS safety categories. The extract had no major toxicity that resulted in death. The animals' body weight, food, and water intake did not shift between the dosage classes of 300 mg/kg and 2000 mg/kg body weight). At the maximum dose of 2000 mg/kg body weight, no mortality was observed, demonstrating that the hydro-ethanolic extract of *Tricholepis glaberrima* has no substantial toxic impact in mice. There is a need for development of appropriate pharmaceutical product of HETG, considering the previous therapeutic effects elucidated in previous research and the tolerability shown in the current report.

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