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PRELIMINARY PHYTOCHEMICAL SCREENING AND EVALUATION OF ACUTE ORAL TOXICITY STUDY OF SANDHIVAATAARI GUTIKA – A HERBOMINERAL DRUG ON EXPERIMENTAL RATS

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ABSTRACT

Sandhivaataari gutika – a herbomineral drug used in the treatment of osteoarthritis was evaluated in an acute oral toxicity study in a Male Wister rats. Animals were divided into two groups of seven animals each. One group was administered with 2000mg/kg body weight and other group was administered with 5000mg/kg body weight in acute oral toxicity study. The text substance was administered in single dose leval.Signs of toxicity were observed every hour for the first 6 hrs and every day for 14 days. There were no mortalities or clinical signs observed in rats in the acute oral toxicity study. The high no observed adverse effects level (NOAEL) value of 2000mg/ kg and 5000mg/ kg body weight in both groups implies that the drug could be safe. The drug is tested for preliminary phyto-chemical screening It is positive for Cardiac glycosides, Anthroquinone glycosides, Tannins and phenols and negative for Alkaloids, Carbohydrates, proteins and Flavonoids

KEYWORDS: Sandhivaataarigutica, Acute toxicity, Herbomineral formulation.

INTRODUCTION

The drug used for acute toxicity studies is the herbo mineral drug named sandhivaataari gutika which is the combination of three different herbomineral substances. So the drug is

said to be herbomineral formulation which posses many therapeutic effects on human body. Acute toxicity studies involve the administration of a single dose of test compound and are usually followed by 14 days of observation including the recording of clinical signs (e.g. behavior, body weight), duration, and reversibility of the toxic effect.

Regulatory authorities require data from acute toxicity studies for the registration of any pharmaceutical intended for human use. Traditionally, the information obtained from these studies has been used to set an appropriate dose level for repeat dose studies in animals and to support the effects of overdose in humans. The aim of this study was to evaluate the safety profile of the herbomoniral anti- arthritic preparation sandivaataarigutica after a single dosing to observe adverse effects.

Preparation of sandhivaataari gutika

The drugs purified Hingulam (Cinnabar), Guggulu (commiphoramukul) and Bola (Commiphora mol mol) are made into powder. This powder is pounded in go dugdha (cow's milk)for one day. Afterwards dried and powdered and made into pills in the dose of 125mg.[1]

MATERIALS AND METHODS PREPARATION OF EXTRACTS

First the powered drug was subjected to extraction. The extracts were prepared by using hot air percolation technique using soxhlet apparatus, a process of extraction of a drug with a solvent with several daily shakings. This method was based on the extraction of active constituents by simple hot air percolation using water as solvent.50g of the powdered material was placed inside a thimble supported by cotton pads which is loaded into the main chamber of the Soxhlet extractor. The Soxhlet extractor is placed onto a flask containing the extraction solvent. The Soxhlet is then equipped with a condenser.

- The solvent is heated to reflux. The solvent vapour travels up a distillation arm, and floods into the chamber housing the thimble of solid. The condenser ensures that any solvent vapour cools, and drips back down into the chamber housing the solid material.
- The chamber containing the solid material slowly fills with warm solvent. Some of the desired compound will then dissolve in the warm solvent. When the Soxhlet chamber is almost full, the chamber is automatically emptied by a siphon side arm, with the solvent running back down to the distillation flask. This cycle may be allowed

to repeat many times, over hours or days.

- During each cycle, a portion of the non-volatile compound dissolves in the solvent. After many cycles the desired compound is concentrated in the distillation flask.
- After 24 hrs, the water extract was filtered and the marc was repeated two more times with the same solvent for effective extraction. Extract was concentrated by open air drying. And the acquired extract was stored in desiccators.

- **A schematic representation of extraction**

50g of powder was percolated with 500ml water as solvent for several times

↓

Filtered, extract is concentrated by distill

↓

Dried in desiccators

↓

Resulting material was found to weigh as follows

- Water-30gm

Preliminary phytochemical screening

Table no: 1

Chemical constituent	**Observation** [2,3,4,5]
Alkaloids	negative
Carbohydrates	negative
Proteins	negative
Flavanoids	negative
Cardiac glycosides	positive
Anthra quinone Glycosides	positive
Saponin glycosides	positive
Tannins &Phenols	positive

Acute toxicity studies

Experimental animals and Institutional Animal Ethical Committee (IAEC) clearance

Male Wistar rats (150-200g) were purchased from Mahaveer enterprises, Hyderabad. The animals had free access to standard rodent pellet diet with water *ad libitum*. Animals were habituated to laboratory conditions prior to experimental protocol (22 ± 3ºC temperature, 50-60% humidity). All the protocols and experiments were conducted in strict

compliance according to guidelines provided by Committee for the Purpose of Control and Supervision of Experiments on Animals(CPCSEA).The approval (Proposal No.IAEC/NCP/07/09) of the Institutional Animal Ethical Committee (IAEC) Vishnu institute of pharmaceutical education and research was taken prior to the experiments.

Grouping and dosing

Animals were divided into two groups of seven animals each. One group was administered with 2000mg/kg body weight and other group was administered with 5000mg/kg body weight.

Administration of doses

The sandhivaataari gutika was administered in a single dose by gavage using a stomach tube or a suitable intubation canula. Animals should be fasted prior to dosing (e.g. in mouse, food but not water should be withheld for 3-4 hours). Following the period of fasting, the animals should be weighed and the test substance administered. After the substance has been administered, food may be withheld for 1-2 hours in mice. Where a dose is administered in fractions over a period of time, it may be necessary to provide the animals with food and water depending on the length of the period. Groups of animals of a single sex are dosed in a stepwise procedure using the fixed doses of 5, 50, 300 and 2000 mg/kg (exceptionally an additional fixed dose of 5000 mg/kg may be considered. The initial dose level is selected on the basis of a sighting study as the dose expected to produce some signs of toxicity without causing severe toxic effects or mortality. Clinical signs and conditions associated with pain, suffering and impending death are described in detail in a separate OECD Guidance Document.[8] Further groups of animals may be dosed at higher or lower fixed doses, depending on the presence or absence of signs of toxicity or mortality. This procedure continues until the dose causing evident toxicity or no more than one death is identified or when no effects are seen at the highest dose or when deaths occur at the lowest dose. Exceptionally and only when justified by specific regulatory needs, the use of an additional upper fixed dose level of 5000 mg/kg may be considered. For reasons of animal welfare concern, testing of animals in GHS Category 5 ranges (2000-5000mg/kg) is discouraged and should only be considered when there is a strong likelihood that results of such a test have a direct relevance for protecting human or animal health or the environment. Period of at least 24 hours will be allowed between the dosing of each animal. All animals should be observed for at least 14 days.[6,7]

Table no.2. Administration of doses to first group

S.No	Weight of animal(g)	Weight of drug (mg/kg)	Volume of dose for each animal (ml)
1	175	0.35	0.71
2	180	0.36	0.73
3	170	0.34	0.69
4	168	0.33	0.67
5	180	0.36	0.73
6	170	0.34	0.69

n=6 Dose = 2000mg/kg body weight

Table no. 3. Administration of doses to second group

S.No	Weight of animal(g)	Weight of drug (mg/kg)	Volume of dose for each animal (ml)
1	190	0.95	1.84
2	190	0.95	1.84
3	180	0.9	1.74
4	190	0.95	1.84
5	220	1.1	2.13
6	210	1.05	2.03

n=6 Dose = 5000mg/kg body weight

Administration of sandhivaataari gutika (2000mg/kg) showed no change in body weight of animals. Convulsions and tremors were not found. Food and water intake were also found to be normal.

DISCUSSION

Phytochemicals are non-nutritive plant chemicals that have protective or disease preventive properties. Phytochemical screening is a process of tracing plant constituents. Sandhivaataari gutika was found to have carbohydrates, proteins and tannins as its phytochemical constituents. It is clear that the strategy for toxicity testing has changed significantly over the years in order that early toxicology information can help support decisions on the best compounds to progress as potential human medicines. Lower dose (2000mg/kg body weight) has not shown changes in body weights of rats. It has not shown any convulsions or tremors. Food and water intake of animals was also found to be normal. Higher dose (5000mg/kg) has shown slight decrease in body weight of animals which was not significant. It has not shown any convulsions and tremors. Food and water

intake of animals was also found to be normal.

CONCLUSION

Sandhivaataari gutika was found to have carbohydrates (aqueous extract), proteins (aqueous extract), tannins and phenols (aqueous extract) as their phytoconstituents. Lower dose of sandhivaataari gutika (2000mg/kg body weight) and higher dose (5000mg/kg body weight) did not produce any clinical signs of toxicity and death of animals.

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