Available online www.jocpr.com

Journal of Chemical and Pharmaceutical Research, 2016, 8(12):215-217

Research Article

ISSN : 0975-7384
CODEN(USA) : JCPRC5

Acute Toxicity Study of Siddha Formulation- Amirtharasa Mathirai

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ABSTRACT

Administration of herbal drugs to cure diseases in humans is since time immemorial. Each and every civilization has its own culture and medicine, are called as traditional systems. Siddha system of medicine is one of the traditional system belongs to Dravidian race belongs to southern part of India. This system of medicine is using herbals, metals and minerals as the raw drugs to make medicines. Recent scientific trends insisting that administration of metals in human usage should undergo the toxicity studies. Amirtharasa mathirai is one of the siddha formulation made up of heavy metal mercury and sulphur. Amirtharasa mathirai (ARM) is studied for acute toxicity. The results are the ARM did not exhibit any mortality in mice. No behavior changes and weight reduction of mice in this study. Reflexes were found to be normal before and after the drug administration. In necropsy, all the internal organs are appeared normal. Hence the siddha formulation ARM is safe and recommended for human usage.

Keywords: Siddha system; Amirtharasa mathirai; Toxicity studies

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INTRODUCTION

Siddha system of medicine is one of the oldest systems in Indian system of medicine. Medicines, which made up of metals and minerals in addition with herbals are usual one in this system. Metals which were converted into medicine are very common since from metal era. But there has always been a debate on the use of these preparations because most of the metals are toxic to vital organs. Toxicity studies for those drugs which are having metals should undergo toxicity studies before human usage. Applications of existing modern technologies including nanotechnology can help in establishing the nontoxic nature of these metallic preparations which may be due to various purification steps employed during the preparation process including ashing. Because of these processes, metal acquires nanoparticle size, nontoxic in nature. But when come to acute and chronic toxicity studies still depend on studies which carry out in guinea pigs and mice. Because of there is always some variance in vitro and in vivo studies. The drug Amirtharasa Mathirai (AM) was selected from the classical Siddha literature Agasthiyar Vaithiya Chinthamani Venbaa 4000 ennum Mani 4000 , part -2 [1].

Preparation of the drug

The raw materials included in the formulation are, Mercury Sulphur and Indigofera tinctoria were procured and were identified and authenticated by the experts, National Institute of Siddha, Chennai. The specimen sample of each ingredient was labeled separately and kept in the lab for future reference. The purification process was done according to the procedures mentioned in the classical Siddha literature.

MATERIALS AND METHODS

Principle

Acute toxicity was carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound the study duration will be 14 days [2-7].

Animal species	:	Swiss albino mice
Age / Weight / Size	:	6 weeks. Mice-20-25 gms.
Gender	:	Both male and female [8]
Number of Animals	:	Mice: 10
Acclimatization Period	:	7 Days
Clinical dose	:	260 mg\day

S.No	Group	No of mice
1	Vehicle control (saline)	10 (5 male, 5 female)
2	Toxic dose 10X therapeutic dose(4.68mg)	10 (5 male, 5 female)

Test animals

Test animals were obtained from the animal laboratory of the King institute, Chennai and stocked at National institute of siddha, Chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c).The animals had free access to water and standard pellet diet (Sai Durga foods pvt.ltd, Bangalore).The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. (1248/ac/09/CPCSEA/February/ 2012)

Route of administration

Oral route was selected, because it is the normal route of clinical administration.

Test substance and vehicle

The Amirtharasa mathirai is Black in colour. The test substance is insoluble in water, in order to obtain and ensure the uniformity in drug distribution the drug is dissolved by aqueous Tween 80 solution (10%).

Administration of doses

Amirtharasa mathirai was suspended in aqueous Tween 80 solution (10%), with uniform mixing and it was administered to the groups in a single oral dose .The control groups were received equal volume of the vehicle. The animals were weighed before giving the drug. The dose level was calculated according to body weight, and surface area. Since the clinical dose was 260mg\day it was converted to animal dose (4.68mg) and then administered. The principle of laboratory animal care was followed [9-12].

Observations

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration [9]. The animals were monitored for behavioral parameters like

1. Awareness: Alertness, Visual placing, Stereotype, Passivity
2. Mood: Grooming, Restlessness, Irritability, Fearfulness
3. Motor activity: Spontaneous activity, Reactivity, Touch response, Pain response.

Animals were observed for body weight and mortality for 14 days. If animals died during the period of study, the animals were sacrificed. At the end of the 14^{th} day all animals were sacrificed and necropsy was done [13].

Body weight

Individual weight of animals was determined before the test substance was administered and daily for 14 days. Weight changes were calculated and recorded. At the end of the test, surving animals were weighed and sacrificed [11].

RESULTS

Amirtharasa mathirai at the dose 4.68mg/animal did not exhibit any mortality in mice. No behavior changes were noted for the first 4 hours and for the next 24 hours and throughout the study period of 14 days. No weight reduction

was noted before and after the acute study duration. Reflexes were found to be normal before and after the study. All other observations were found to be normal before and after the study. In Necropsy, the organs of the animal such as, Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

DISCUSSION

The Golden rule is while preparing siddha formulation we should strictly follow the purification steps and the grinding hours as per classical literature. Whatever may be the medicine made up of herbals or metals should apply this golden rule didn't exhibit toxicity. This study proves this and safe. The siddha formulation ARM is recommended for human usage.

ACKNOWLEDGEMENT

The author expresses his gratitude to The Director, National Institute of Siddha, Chennai.

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