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Original Article

Acute Toxicity Study of Novel Ayurvedic Formulation Siddha Shalmali Kalpa (Classical *Shalmali malabarica* Formulation) in Wistar Rat *in vivo* Experimental Study

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ABSTRACT

Background: Traditional Ayurvedic Herbal remedies have long been used to improve and revitalize reproductive health. *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation) is one such formulation that has long been praised for its aphrodisiac qualities. Its safety profile is still not well supported by scientific research, nevertheless. **Objectives:** In order to lay the groundwork for next pharmacological and clinical studies, this study sought to assess the acute oral toxicity of *Siddha Shalmali Kalpa* in rats. **Materials and Methods:** As per OECD Guideline 423, the study was carried out by giving a single oral dosage (2000 mg/kg body weight) of a formulation. Over the course of 14 days, the animals were monitored for physiological indicators, behavioural changes, clinical symptoms, and mortality. Weekly body weight measurements were made. Biochemical indicators of kidney and liver function were measured on day 15. The stomach, lungs, liver, and spleen were among the vital organs that underwent histopathological analysis. **Results:** None of the treated animals showed signs of death or serious harmful consequences. Minor poisoning symptoms, like brief shaking and slight body tone changes, were noticed but went away on their own. Histopathological analyses of the organs revealed no anomalies, and biochemical markers stayed within normal ranges. Over the course of the trial, the body weight progressed normally. **Conclusion:** At 2000 mg/kg, *Siddha Shalmali Kalpa* showed a good acute safety profile and was determined to be non-toxic. These results validate additional preclinical and clinical testing and provide credence to their safe use as possible herbal aphrodisiacs.

Keywords: Acute Toxicity Study, Aphrodisiacs, Classical *Shalmali malabarica* Formulate, *Siddha shalmali kalpa*, Vajikarna.

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INTRODUCTION

For thousands of years, traditional formulations and herbal remedies have been essential to people's health and well-being. Reproductive and sexual health is one of the main areas of emphasis in these systems, and aphrodisiac formulas have long been used to support vitality, stamina, hormonal balance, and general quality of life in addition to improving sexual performance (Singh, 2011; Vidhate *et al*., 2025). Due to an increase in stress-induced sexual dysfunction, erectile dysfunction, infertility, and lifestyle-related reproductive problems in both men and women, there is a greater need than ever for safe and effective aphrodisiacs.

Reproductive health issues have alarmingly increased worldwide due to a number of factors, including sedentary lifestyles (Shindel *et al*., 2007), mental stress, bad eating habits, environmental contaminants, and excessive use of synthetic drugs (Laumann *et. al*.,1999). Pharmaceutical treatments like phosphodiesterase-5 inhibitors (like sildenafil) are commonly utilized, but their long-term usefulness is limited by their frequent negative side effects, which include headaches, dizziness, hypotension, and reliance (Kloner, 2000).

According to traditional beliefs, these compositions, called Vajikarana in Ayurveda, improve libido, boost sperm quality and quantity, nourish the reproductive tissues (Shukra Dhatu), and revitalize the body's internal systems (Roushan, 2019). Crucially, they don't just enhance transient performance; they also seek to promote health and restore equilibrium from the inside out. Many of these herbal treatments, however, have not received thorough scientific validation despite their long history of usage, especially with regard to safety and toxicity (WHO, 2007), which is necessary for their adoption in international evidence-based

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medicine (Parasuraman, 2011). *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation), (Kaviraj, 2014). a traditional polyherbal remedy based on *Shalmali malbarica* (also called the silk cotton tree), is one such formulation. This mixture, which has long been known for its rejuvenating and aphrodisiac properties, has been used to cure ailments like weariness, premature ejaculation, sexual weakness, and general debility. *Shalmali malabarica* varied phytochemical profile, which includes flavonoids, saponins, sterols, and tannins - compounds with adaptogenic, antioxidant, and libido-boosting qualities is responsible for its pharmacological potential (Bhargava *et al*., 2011). Traditional methods are becoming more and more popular among consumers due to their perceived safety over synthetic medications as well as their cultural resonance (Malviya *et al*., 2011).

The current study was conducted to evaluate the acute oral toxicity profile of *Siddha ShalmaliKalpa*, in order to close this gap. Following OECD guideline 423 (OECD, 2001)., animals were monitored for clinical symptoms of toxicity, behavioural abnormalities, physiological modifications, and death over a 14-day period after receiving a single high dosage of 2000 mg/kg body weight orally.

The findings of this study are an essential first step in developing a toxicological safety profile for the formulation. The prospective use of the formulation in upcoming clinical research and therapeutic applications is supported by the lack of mortality and the observation of only minor, reversible toxic symptoms, which point to a high safety margin.

MATERIALS AND METHODS

Study Design

In vivo Experimental Study by following OECD Test Guideline 423 using Wistar albino rats. Experimental *in vivo* Study: The single-dose toxicity study design involved a total of six animals. Feed intake and body weight were recorded once weekly throughout the experimental period. Using Wistar albino rats, this study attempts to evaluate the Acute Oral Toxicity and Safety profile of formulation of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation) (Kaviraj, 2014). The study is intended to assess the possible morbidity, mortality, and physiological alterations linked to a single high-dose administration formulation and is conducted in accordance with OECD Test Guideline 423 for Acute Oral Toxicity testing (OECD, 2001).

Ingredientsof the test drug

The main element is*Siddha ShalmaliKalpa*, a classic polyherbal formulation made in accordance with Ayurvedic pharmacopeial norms, is *Shalmali malabarica*. Other ingredients were as - *Shudha Parad a* (Jaiswal *et al*., 2022), *Shudha Gandhak* (Panigrahi,2018). *Bhukushmanda* (*Vidarikanda*) *Churna* (Malipatil, 2014), *Talmuli* (*Krushna Musali*) *Churna*

(Puri,2002).*Dhatri*(*Amlaki*)*Churna*(Kumbhare,2020).*Punarnava Churna* (Hazera, 2016). *Shwet Shalmali Kwatha* (Meena, 2017). *Mahishi Dugdha* (Pathak *et al*., 2022).

Preparation of SidhaShalmaliKalpa (*Shalmali malabarica* Formulation)

A registered Ayurvedic medicine manufacturing facility provided the formulation, which was made under Good Manufacturing Practices (GMP). The traditional *Sidha ShalmaliKalpa* (Classical *Shalmali malabarica* Formulation) (Kaviraj, 2014) (Table 1)., is prepared as follows:

Shudha Parada (50 g) and Shudha Gandhaka (25 g) taken in Khalwayantra (Mortar and Pestle) triturated well to prepare Kajjali (Black Sulphide of Mercury). Fine Powders of *Bhukushmanda* (*Vidarikanda*) Churna, *Talmuli* (*Krushna Musali*) Churna, *Dhatri* (*Amlaki*) Churna, *Punarnava Mula Churna* (200 g) were added one by one and triturated in Khalwayantra (Mortar and Pestle). After proper mixing this *churna* give Bhavana (Trituration) of *Shwet Shalmali Kwatha* (Decoction of *Shalmali malabarica*) and *Mahisha Dugdha* (Buffalo Milk) each 7 times and dried in shadeafter making tablets and Stored in Glass Bottle (Kaviraj, 2014).

Test formulations Preparation

The test formulations were diluted with the help of 0.5% CMC Solution and administered. Fresh suspensions were prepared on the day of administration.

Animal Husbandry

The study included a total number of six Wistar albino rats (three males and three females), each weighing between 150-180 g. The study used Wistar albino rats that were eight weeks old when treatment started. Within each sex group, the animals' weight variance did not surpass ±20% of their mean body weight. One species that is advised for use in preclinical toxicity investigations is the Wistar albino rat. The animals were housed in sterilized polycarbonate cages, and the animal rooms were maintained under standard husbandry conditions. The temperature was regulated at 22 ± 30°C with a relative humidity ranging from 30% to 70%. A 12-hr light and 12-hr dark photoperiod cycle was consistently maintained. The animals were fed on pelleted feed containing standard composition of all macro and micronutrients. Purified water collected through aqua guard. Animals were identified by Body marking. Each cage was identified with individual cage

With a wealth of historical data accessible for comparison, they have been used extensively throughout the industry to assess product safety.

Animal Grouping for Acute Oral toxicity study: Three male and three female rats received a single oral dosage of the traditional *Siddha ShalmaliKalpa* formulation (Classical *Shalmali malabarica* Formulation) at a rate of 2000 mg/kg body weight. Because it is the suggested method of administration to humans, the oral route has been selected. One of the frequently suggested methods for toxicity testing is the oral route.

Dosing and Duration of Siddha Shalmali Kalpa (Classical Shalmali malabarica Formulation): The Acute Oral Toxicity study was performed following the OECD Test Guideline 423 (Acute Toxic Class Method). A single oral dose (2000 mg/kg body weight), on first Day of experiment of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation) was given to overnight-fasted animals using a gavage needle. And all animals were observed up to next 14 days.

Ethical statement

This experiment was carried out by following OECD guidelines 423. All the standards of ethical consideration were strictly followed during the experiment.

Ethical approval was obtained from the both the institutional ethical committee and the IAEC prior to the initiation of experimental procedures.

IEC clearance Letter - Ref. No.: MGACHRC/IEC/Dec-2022/622 Date - 07/12/2022.

IAEC clearance Letter - Ref. No.: BIRD/12/2024/06 Date - 12/12/2024.

Statistical Analysis

All Data obtained during Acute Oral Toxicity study was recorded, summarized in tabular form, which includes - Food Intake and Body weight (Table 2), Clinical Observation (Table 3), analysis - Liver Function Tests and Kidney Functions Tests (Table 4) of each individual also Histo-pathological observations (Figure 1) of organs such as Liver, Kidney, Spleen, Stomach, Lungs of single rat was performed. And then analyzed by qualitative and quantitative comparison in between the group.

As per OECD guidelines, this limit test at one dose level of 2000 mg/kg body weight was carried out with six animals (three males and three females), so no any specific statistical test was applied here.

RESULTS

Over the course of 14 days after oral treatment to *Wistar albino* rats, the result of the acute toxicity research of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation) was methodically documented. In order to evaluate potential toxicological effects and ascertain the safety profile of the formulation, observation was made focusing on physiological activity, such as food intake, body weight changes, clinical symptoms, mortality, biochemical parameters, and histological discoveries.

Physiological Function

Consumption of Food

In order to evaluate the overall health and possible systemic toxicity of the test formulation, food consumption was tracked as a crucial physiological indicator. Changes in food intake may be a precursor to negative consequences such as systemic organ malfunction, metabolic imbalance, or gastrointestinal discomfort. The details of food intake are presented in Table 2.

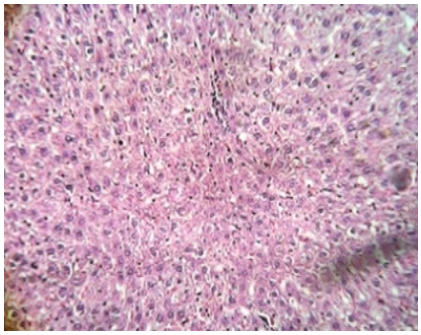

Figure 1: Liver.

Table 1: Ingredients of Siddha Shalmali Kalpa (Classical *Shalmali malabarica* Formulation).

Drug Name	Latin Name	Part used	Quantity
Shudha Parada	Purified Mercury	Mercury	2 parts
Shudha Gandhak	Purified *Sulfur*	Sulphur powder	1 part
Bhukushmand (Vidarikanda Churna)	Pueraria tuberose	Roots	1 part
Talmuli (Krushna Musali Churna)	Curculigo orchioides	Roots	1 part
Dhatri (*AmlakiChurna*)	Emblica officinalis	Fruits	1 part
Punarnava Churna	Boerhaavia diffusa	Roots	1 part
Shwet Shalmali Kwatha	Shalmali malabarica	Roots	7 Bhavana
Mahishi Dugdha	Buffalo Milk	Milk	7 Bhavana

Table 2: Summary of rats' Food intake and body weights recorded during the acute oral toxicity study of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation).

Sex	Animal ID	Food Intake		Body weight	
		Day		Day	
		0	14	0	14
Female	1	22 g	20 g	220 g	228 g
	2			231 g	239 g
	3			218 g	228 g
Male	4	25 g	21 g	235g	243 g
	5			238 g	239 g
	6			215 g	222 g

Table 3: Summary of rats' Clinical Observation recorded during the acute oral toxicity study of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation).

Sex	Female			Male		
General Clinical Signs	1	2	3	4	5	6
Assessments of posture	0	0	0	0	0	0
Signs of Convulsion (Limb paralysis)	0	0	0	0	0	0
Shivering	*	0	0	0	0	*
Body tone	0	0	0	0	0	*
Lacrimation	0	0	0	0	0	0
Salivation	0	0	0	0	0	0
Tremor	0	0	0	0	0	0
Change in skin color	0	0	0	0	0	0
Piloerection	0	0	0	0	0	0
Defecation	0	0	0	0	0	*
Sensitivity response	0	0	0	0	*	0
Locomotion	0	0	0	0	0	0
Muscle gripness	0	0	0	0	0	0
Rearing	0	0	0	0	0	0
Food intake	0	0	0	0	0	0

0 = Normal; X = Not survived; * = Sign of toxicity.

The food intake was not significantly decreased as well as fluctuated abnormally was not recorded during the research period. Anorexia or gastrointestinal toxicity were not present in any of the animals, as evidenced by their normal appetite and feeding habits. Since there was no evidence of appetite or eating behaviour reduction related to the formulation, this finding supports the preliminary safety of the test formulation at the administered dose of 2000 mg/kg body weight.

Body Weights as a Physiological Activity

Because, it is a sensitive predictor of the overall health and physiological reaction of animals to test chemicals, body weight monitoring is an essential criterion in toxicity research. Significant weight loss could be an indication of organ malfunction, metabolic disruption, or systemic toxicity. Each rat's body weight was measured once a week in the current investigation, on Day 0 (before treatment) and Day 14 (at the conclusion of the observation period). The comparative body weights are presented in Table 2.

All animals exhibited a gradual increase in body weight over the 14-day period, with no instances of weight loss or stagnation, except for a marginal increase in one male rat (Animal 02). This gain in body weight suggests that the formulations did not produce any adverse effects that could interfere with normal growth and metabolism.

Additionally, the conclusion that the test drug -*Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation) was not caused any systemic toxicity at the tested dose of 2000 mg/kg body

Table 4: Summary of rats' Biochemistry analysis - Liver Function Tests and Kidney Functions Tests recorded during the acute oral toxicity study of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation).

Animal Sex	Animal ID	Liver Function Tests			Kidney Functions Tests	
		SGOT (mg/dL)	SGPT (mg/dL)	ALP (mg/dL)	Creatine (mg/dL)	Urea (mg/dL)
Female	1	78	53	242	0.37	7.28
	2	61	37	203	0.34	6.89
	3	67	55	217	0.42	5.23
Male	4	74	42	189	0.39	8.13
	5	79	51	236	0.51	7.51
	6	65	29	192	0.49	5.69

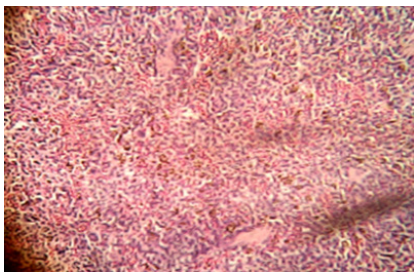

Figure 2: Spleen.

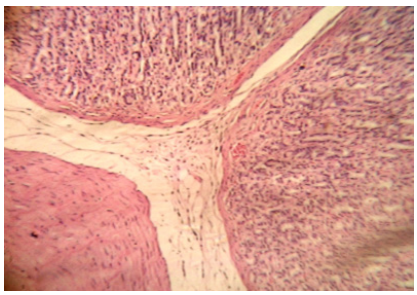

Figure 3: Stomach.

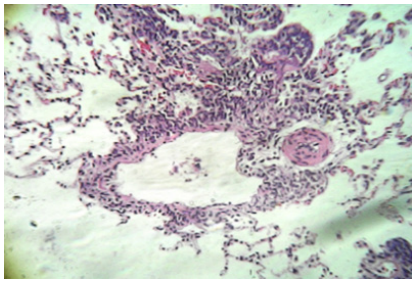

Figure 4: Lungs.

weight is supported by the lack of statistically or physiologically significant weight loss.

Clinical Observations

An essential part of acute toxicity studies is systematic clinical observation, which looks for any unfavourable physical or behavioural symptoms that can appear after a test chemical is administered. Early detection of systemic, neurological, or local toxicity is aided by observations. Every animal in this trial was monitored separately for the first half hour after administration, then at regular intervals for the first four hours and then once a day for the next 14 days. Assessments of general behaviour, posture, motor activity, reflexes, autonomic and central nervous system functions, and any unusual physical symptoms were all part of the observations. Each animal in the test group had its findings documented using a clinical observation checklist. The following criteria were noted as mentioned in Table 3.

During the 14-day period, no deaths were noted. One female (Animal 1) and one male (Animal 3) experienced mild shivering for a brief period of time; this could have been brought on by stress or a temporary metabolic adjustment to the formulation. Male 3 experienced an episode of inconsistent faces and a slight decrease in body tone. Male 2 showed a mild sensitivity response, or an increased reactivity to touch or stimulation.

These mild and transient symptoms went away on their own without help and were not accompanied by any notable behavioural abnormalities or systemic toxicity. Accordingly, the results indicate that there was no significant clinical toxicity seen with the *Sidha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation), which was well tolerated at a level dose of 2000 mg/kg body weight.

Pre-Terminal Deaths

Pre-terminal deaths in acute oral toxicity studies are defined as any death that takes place before the observation period's planned end (14 days), frequently as a direct result of the test substance's harmful effect. To identify early mortality and evaluate dose-dependent risk, close observation is essential in the initial hours and days after medication. All of the animals in this study were extensively monitored for indications of toxicity and death after receiving *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation) at a limit dose of 2000 mg/kg body weight. Right after the dose half an hr, an hour, two hours, and four hr; After that: twice a day (morning and evening) for a period of 14 days of observation. Every day, the survival status of every animal was evaluated.

Over the course of the 14-day post-treatment observation period, no mortality was noted in any of the animals, regardless of sex. The lack of pre-terminal fatalities is a clear sign that the test formulation, the *Siddha Shalmali Kalpa* (classical *Shalmali malabarica* formulation), did not cause any fatal side effects at the dosage that was given.

Analysis of Biochemistry

In order to determine the possible effects of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation) on hepatic and renal functions-two important markers of systemic toxicity - biochemical parameters were assessed at the end of the 14-day study period. Under light anaesthesia, blood samples were obtained via retroorbital puncture, and an automated biochemistry analyser was used for analysis.

Serum Alkaline Phosphatase (ALP), SGOT (AST), and SGPT (ALT), which are sensitive indicators for hepatic injury or dysfunction, were measured as part of the Liver Function Test (LFT). The comparative analysis is presented in Table 4.

All liver enzyme levels were within normal physiological limits for *Wistar albino* rats. No statistically significant elevation in SGOT, SGPT, or ALP was noted in any animal, indicating the absence of hepatocellular toxicity from the test formulation at the tested dose.

Kidney Function Test (KFT): Renal function was reviewed by measuring serum levels of Creatinine and Urea**,** both of which are established indicators of glomerular filtration and renal excretory function. The results are documented in Table 4.

All values for creatinine and urea were within the expected normal range for the species. No significant deviation was observed, suggesting preserved renal function and absence of nephrotoxicity in the test group.

Histopathology

At the conclusion of the study, a gross necropsy was performed on one animal (male rat). Tissues from the lungs, stomach, liver, and spleen were collected and fixed in 10% neutral-buffered formalin. They were then processed using standard histological techniques, sectioned, and stained with Hematoxylin and Eosin (H&E) for microscopic examination. The details of histopathological observations are presented in Figures 1-4.

The results of the biochemical tests were supported by histopathological analysis, which verified that there were no morphological or structural anomalies in the main organs. At the studied acute dosage of 2000 mg/kg, *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* Formulation) is non-toxic to the kidneys and liver, according to the combined biochemical and histopathological results.

DISCUSSION

According to OECD Guideline 423 (Acute Toxic Class Method), this study evaluated the Acute Oral Toxicity of the traditional Ayurvedic formulation *Sidha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation) in *Wistar albino* rats at a single limit dose of 2000 mg/kg body weight. With ancient claims of use as aphrodisiacs and rejuvenating agents in *Ayurvedic* medical systems, this inquiry offers preliminary insights into the safety profile of formulation. No mortality or pre-terminal deaths were noted in either the male or female rats administered with this formulation for the whole 14-day observation period. Low acute oral toxicity is indicated by the lack of death at a dose of 2000 mg/kg body weight. A few animals had mild and temporary clinical symptoms, including shivering, a minor decrease in body tone, and sporadic changes in faeces. These symptoms, however, were non-lethal, dose-limiting, and went away on their own without the need for medical attention. Salivation, lacrimation, convulsions, tremors, or notable behavioural abnormalities were not detected, which further suggests that this formulation was well tolerated.

In rodents, body weight is a sensitive measure of both systemic toxicity and overall health. During the study period, all of the animals showed normal weight gain, which is in line with the *Wistar* rats' typical growth pattern. Significant weight loss or growth stagnation was not observed, suggesting that the formulation did not disrupt regular metabolism or result in systemic toxicity. To assess hepatocellular integrity, biochemical markers including SGOT (AST), SGPT (ALT), and Alkaline Phosphatase (ALP) were evaluated. No statistically significant increases were noted, and all values stayed within physiological bounds. These results imply that the formulation has any hepatotoxic effects.

All of the animals' serum creatinine and urea levels, which are indicators of kidney function, were also within normal ranges. The test chemicals did not have nephrotoxic effects, as confirmed by renal parameters that were compatible with intact glomerular filtration and excretory function. No pathology abnormalities were found during the histological examination of vital organs such as the liver, stomach, lungs, and spleen. There were no indications of inflammation, necrosis, bleeding, or degenerative alterations, and the tissue architecture was unaltered. This demonstrates that the formulation did not cause any histomorphology changes in essential organs and supports the biochemical results.

Due to growing awareness of infertility, stress-related libido loss, male and female sexual dysfunction, and lifestyle-related reproductive concerns, there is a growing demand for safe, natural aphrodisiacs in the modern world. Traditional aphrodisiacs frequently have side effects or restrictions when used over an extended period of time. Because of their traditional use, natural nature, and few side effects, Ayurvedic Classical formulations are becoming more and more popular as safer substitutes.

Shalmali malabarica, which has adaptogenic and antioxidant qualities, is a component of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation), which has long been used to improve vitality, semen quality, and sexual stamina. Nevertheless, prior to clinical translation or formulation into contemporary dosage forms, scientific validation of safety is crucial, even in cases of long-standing traditional use. the traditional forms of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation) have a strong preliminary safety validation based on the study's findings. This study fills a crucial gap by offering scientific proof of acute safety, thereby setting the stage for sub-acute, chronic toxicity, and pharmacological efficacy investigations. This is especially important given the increased interest in herbal and traditional formulations.

In this study, *Wistar albino* rats were used to evaluate the Acute Oral Toxicity of the *Siddha Shalmali Kalpa*, which is based on *Shalmali malabarica*. Due to its aphrodisiac and restorative properties, this formulation has been employed for a long time in classical ayurvedic formulation. Notwithstanding their historical appeal, their wider clinical application and incorporation into contemporary therapeutic frameworks required scientific confirmation of their safety through precise toxicological investigations.

Both male and female rats were given a single, high dose of 2000 mg/kg orally as part of this investigation, and all of the animals were observed for the next 14 days. Amazingly, there was no mortality at all, and in a small number of cases, there were only mild, transient symptoms of poisoning, such short bouts of shivering or tiny variations in body tone. Crucially, every animal continued to eat, behave, and grow body weight normally, indicating that there was no systemic poisoning.

The results of biochemical tests, such as the Kidney Function Tests (creatine and urea) and the Liver Function Tests (SGOT, SGPT, and ALP), were within normal physiological bounds. These results suggest that there were no notable hepatotoxic or nephrotoxic effects from the formulation.

On the other hand, *Ayurvedic* aphrodisiacs such as *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation) provide a comprehensive, side-effect-free substitute; yet, the absence of scientific safety data has prevented their broader adoption. Thus, by offering solid, lab-based proof of acute safety, this work closes that crucial gap and promotes more investigation and advancement. This work's significance stems from its capacity to scientifically validate conventional wisdom, opening the door for next clinical trials and pharmaceutical research, including sub-acute and chronic toxicity testing. Furthermore, the results back up initiatives to improve dose forms, standardize the formulation, and eventually encourage its safe incorporation into contemporary complementary medicine systems.

CONCLUSION

In conclusion, this acute toxicity study provides compelling evidence that *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation) was safe for oral consumption at high doses and cause no significant toxicity in vital organs. This not only supports their traditional use but also opens new avenues for developing them into validated herbal therapeutics for the modern world, especially in the realm of reproductive health and sexual wellness

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ABBREVIATIONS

ALP: Alkaline Phosphatase; **ALT:** Alanine Aminotransferase; **API:** Ayurvedic Pharmacopoeia of India; **AST:** Aspartate Aminotransferase; **CMC:** Carboxymethyl Cellulose; **GMP:** Good Manufacturing Practices; **H&E:** Hematoxylin and Eosin; **IAEC:** Institutional Animal Ethics Committee; **IEC:** Institutional Ethics Committee; **KFT:** Kidney Function Test; **LD_{50}:** Median Lethal Dose; **LFT:** Liver Function Test; **OECD:** Organisation for Economic Co-operation and Development; **SGOT:** Serum Glutamic Oxaloacetic Transaminase; **SGPT:** Serum Glutamic Pyruvic Transaminase; **g:** Gram.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

A single dose Acute toxicity study was conducted as per OECD guidelines 423 to assess the safety of *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation) in *albino wister* rats. The test formulation - *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation), well known for its aphrodisiac property, was orally administered at a dose of 2000 mg /kg body weight only once, followed by 14 days observation of toxicity signs and overall safety assessments. On day 15, Biochemical indicators of kidney and liver function were measured, at the same time one animal was sacrificed as per ethical guideline, for the histopathological organ examination stomach, lungs, liver, and spleen were among the vital organs that underwent histopathological analysis. At this high dose of the *Siddha Shalmali Kalpa* (Classical *Shalmali malabarica* formulation) no any significant toxicity signs were recorded as well as no any histopathological signs of toxicity in vital organs. At 2000 mg/kg, *Siddha Shalmali Kalpa* showed a good acute safety profile and was determined to be non-toxic.

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