



Research Article

Evaluation of Dermal Safety of Pachai Pakku Thailam Using the Draize Test in Rabbits

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Abstract

Traditional Siddha medicine has employed herbal oils such as *Pachai Pakku Thailam* to address skin issues, but scientific confirmation of their safety for skin use is still scarce. This study aimed to evaluate the primary skin irritation potential of *Pachai Pakku Thailam* using the Draize method in albino rabbits. The herbal mixture, derived from green-leaved plants, was applied topically to a shaved 6 cm² section on the backs of the rabbits. Skin reactions were noted and rated for erythema and edema at both 1 hour and 72 hours after application by OECD guidelines. A total of six rabbits were utilized, split into control and experimental groups. The control group was not given any treatment, whereas the test group was administered *Pachai Pakku Thailam*. All animals displayed a score of 0.00 for both erythema and edema at every observation point. The determined Primary Irritation Index (PII) was 0.00, categorizing the formulation as non-irritating. These results verify that *Pachai Pakku Thailam* does not induce skin irritation during acute exposure scenarios, endorsing its historical application for skin conditions. Additional research, encompassing chronic toxicity assessments and human testing, is advised to completely determine its safety profile and support its incorporation into contemporary dermatological practices.

Keywords: *Pachai Pakku Thailam*, Skin irritation, Draize test, Primary Irritation Index, Erythema, Edema, OECD guidelines, Rabbits.

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Introduction

Traditional systems of medicine, including Siddha, Ayurveda, and Unani, have long been central to indigenous healthcare practices, particularly in South Asia. Among these, Siddha medicine, an ancient system primarily practiced in Southern India, extensively relies on plant-based formulations for treating a wide range of ailments. A cornerstone of Siddha medicine is the use of herbal

oils (*Thailams*), such as *Pachai Pakku Thailam*, which are traditionally employed to treat conditions such as skin diseases, musculoskeletal disorders, and inflammatory conditions (1,2).

Pachai Pakku Thailam is an herbal oil derived from green leafy plants (Pachaipakku) and various plant-based components, thought to possess anti-inflammatory, antimicrobial, and wound-healing effects. Although commonly utilized in traditional medicine, there is a deficiency of scientific research assessing the skin safety and toxicity of these formulations. With the increasing worldwide interest in natural and plant-based treatments, it is crucial to assess the safety of these products using modern toxicological methods (3).

Herbal remedies, despite being perceived as safe, can cause skin irritation or allergic reactions due to bioactive phytochemicals, resulting in erythema and edema. The Draize skin irritation test,

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established in 1944, evaluates these effects following topical application of substances(4,5).The Draize test is crucial for evaluating the safety of topical formulations, especially as herbal oils like *Pachai Pakku Thailam* are increasingly used in cosmetics and medicinal products. The findings of this test will contribute to understanding the safety profile of *Pachai Pakku Thailam* and support its wider use in modern dermatological care. Primary skin irritation refers to a reversible inflammatory response following the topical application of a substance, typically characterized by erythema, edema, and other mild pathological changes. This irritation is primarily confined to the furthest layers of the skin, the stratum corneum, without causing systemic toxicity (6). Primary skin irritation arises from chemical agents interacting with skin receptors, activating pro-inflammatory pathways(7).The skin, crucial for toxicological evaluations, necessitates assessing irritation potential in early product development(8). Regulatory frameworks like OECD Test Guideline 404 utilize rabbit models for standardized dermal evaluation (6). Despite *Pachai Pakku Thailam's* traditional anti-inflammatory use, scientific data on its dermal safety is scarce. This study aims to evaluate its skin irritation potential in albino rabbits using the Draize test (9).

Materials and Methods

Preparation of *Pachai Pakku Thailam*

Pachai Pakku Thailam is a traditional Siddha herbal oil described in classical Siddha literature, including the text (10). It has been traditionally used by healers in the Kanyakumari region of Tamil Nadu, India, for treating non healing ulcers and burn injuries. Despite its traditional importance, this formulation is not commercially available and is rarely used in current clinical practice. Therefore, the present study aims to scientifically evaluate the efficacy and possible adverse effects of *Pachai Pakku Thailam*. The formulation was prepared following traditional methods, beginning with the collection and authentication of raw ingredients (Table 1). The herbal materials were obtained from country drug stores in Coimbatore, Tamil Nadu, and authenticated by the Siddha Central Research Institute (CCRS), Chennai, under the Ministry of AYUSH, Government of India, to ensure the authenticity and quality of the raw drugs used in the preparation.

Table 1: Ingredients of *Pachai Pakku Thailam*

S.No	Siddha Name	Botanical Name	Part Used / Form	Quantity
1	<i>Varattu Pakku</i>	<i>Areca catechu</i> L	Nut (Dried Areca Nut)	10 g
2	<i>Vellai Kungiliyam</i>	<i>Shorea robusta</i> Gaertn.f.	Resin	10 g
3	<i>Manjal</i>	<i>Curcuma longa</i> L	Rhizome (Turmeric Powder)	10 g
4	<i>Puliyankottai Thol</i>	<i>Tamarindus indica</i> L	Seed coat	10 g
5	<i>Masikkai</i>	<i>Quercus infectoria</i> Oliv	Gall	10 g
6	<i>Kadukkai Thol</i>	<i>Terminalia chebula</i> (Gaertn.) Retz.	Pericarp (Fruit Rind, Seed Removed)	10 g
7	<i>Kaichchukkatti</i>	<i>Acacia catechu</i> (L.f.) Willd.	Heartwood Extract of Catechu	10 g
8	<i>Patchaipakku</i> (unripe) <i>Saru</i>	<i>Areca catechu</i> L	Juice of Unripe Green Betel Nut	1 Liter
9	<i>Thenkai Ennai</i>	<i>Cocos nucifera</i> L	Virgin Coconut Oil	1 Liter

The preparation includes a combination of herbal ingredients, each carefully measured and processed. The ingredients consist of 10g each of various materials are required. The process begins with the preparation of the unripe green betel nut juice, which is collected from local agricultural farms in Vettaikaranpudur, Coimbatore. The betel nut is coarsely ground, and the juice is filtered for use in the formulation. The herbal ingredients are powdered separately and sieved through a fine mesh before being mixed with the betel nut juice and virgin coconut oil. The mixture is then heated in a properly seasoned clay vessel, preferably using firewood to maintain the appropriate temperature. Special care is taken to avoid overheating the oil (which has a smoking point of 171°C) and to prevent charring or contamination from the smoke. The preparation is stirred intermittently, and the mixture is monitored until it reaches the desired consistency and aroma. The final product is filtered while hot through muslin cloth and stored in amber-colored bottles for future use.

Experimental animals

This study used young adult rabbits from the New Zealand White breed. One rabbit was assigned per sample/group. Before the trial began, the animals had at least 7 days to adjust to the controlled laboratory environment. (KMCRT/ReRc/Ph.D/91/2024).

House and Husbandry

All animals were individually kept in metal cages with perforated floors for hygiene. Environmental conditions were controlled at

22 ± 3 °C and 30%-70% humidity. A consistent 12-hour light/dark cycle was maintained. Rabbits received standard feed and water ad libitum, with cages labeled for identification and monitoring.

Experimental Procedure

The Experimental Procedure involved skin preparation by closely clipping hair on rabbits' backs 24 hours before testing. A *Pachai Pakku Thailam* was applied to a 6 cm² area. Skin reactions were assessed and scored daily at 1, 24, and 72 hours using a numerical system (Table 2-4).

Result and Discussion

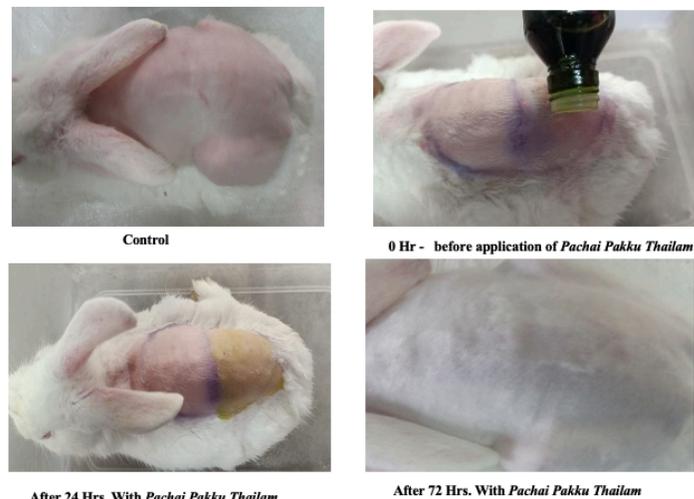
As presented in Table 2- 4, rabbits in the control group exhibited no signs of erythema or edema at either the 1-hour or 72-hour observation points, with an average score of 0.00 for both parameters. This confirms that the application procedure and environmental factors alone did not induce any skin irritation. Similarly, in the test group treated with *Pachai Pakku Thailam*, no observable erythema or edema was noted in any of the three rabbits at both time intervals. All individual scores remained at 0, resulting in a combined irritation index of 0.00. According to the Primary Skin Irritation Index (PII) classification system, a score of 0.0 is designated as Non-Irritant, while higher scores represent increasing levels of irritation. The irritation score was determined using the Primary Irritation Index (PII) by observing erythema (redness) and edema (swelling) at the application site. Each response was assigned a score ranging from 0 to 4 according to its

severity. To obtain the Cumulative Primary Irritation Index (CPII), the erythema and edema scores recorded at the test site were added together and the corresponding scores at the control site were subtracted. The value obtained was then divided by the total number of observations made during the study period to calculate the final irritation score(11). *Pachai Pakku Thailam* can be definitively classified as a Non-Irritant, signifying its safety for external use under the evaluated conditions. (Figure 1).

Table 2: Skin irritation: Primary scoring (Organization for Economic Co-Operation and Development 2002)

Reaction Type	Score	Description
A) Erythema and Eschar Formation	0	No Visible erythema
	1	Very slight erythema (barely perceptible)
	2	Clearly defined erythema
	3	Moderate to marked erythema
	4	Intense information (beet redness to eschar formation)
B) Edema Formation	0	No edema observed
	1	Very slight edema (just perceptible)
	2	Well defined edema
	3	Noticeable Moderate to severe edema
	4	Severe edema (raised more than 1 mm and beyond area of exposure)(Intense erythema with marked edema, which may be associated with skin damage such as ulceration, scab formation, or necrosis.)
Evaluation of primary skin irritation index		
Score	Evaluations	
0.0	Non-Irritant	
0.1-0.4	Irritant	
0.41-1.9	Slight Irritant	
2.0-4.9	Moderate Irritant	
5.0-8.0	Severe Irritant	

Figure 1: Evaluation of Skin Irritancy Test Outcomes Assessing the Impact of Sample on Skin



The results of this study show that *Pachai Pakku Thailam*, a traditional Siddha herbal oil formulation, does not cause skin irritation when applied to rabbit skin in controlled settings. Based on the Draize skin irritation protocol, there were no indications of erythema or edema noted at 1 hour or 72 hours after application. The overall Primary Irritation Index (PII) was determined to be 0.00, categorizing the formulation as non-irritating. These findings align with previous research that emphasizes the skin safety of numerous traditional herbal preparations. Herbal oils utilized in Siddha and Ayurvedic practices are frequently crafted with components recognized for their anti-inflammatory and skin-calming effects. For example, *Oon Poochu Thailam*, a different Siddha oil formulation, was examined for its elemental composition and antimicrobial properties. It was discovered to aid in wound healing without adverse effects, supporting the safety of carefully crafted herbal oils (12). Comparable results have been noted in research on non-Siddha traditional remedies. A recent study assessed the potential for skin irritation of a Thai herbal anti-wrinkle cream infused with *Caesalpinia pulcherrima* flower extract. Rabbit and human patch tests revealed minimal irritation, affirming the product's skin compatibility (13). Another investigation examined the ethanolic extract of *Piper chaba* for allergic reactions in human subjects and reported no adverse responses, supporting its suitability for skin applications (14).

In addition, the antioxidant and soothing properties of traditional herbal extracts such as *Terminalia catappa* have been scientifically validated for inclusion in cosmetic formulations, owing to their non-irritant and anti-inflammatory characteristics (15, 16). While this study confirms the acute dermal safety of *Pachai Pakku Thailam*, it is important to emphasize that further testing, including chronic exposure, sensitization potential, and dermal toxicity under compromised skin conditions, should be conducted to fully establish its safety profile. Moreover, since this study was limited to healthy rabbit skin, clinical trials on human subjects would provide more conclusive evidence for its safety in therapeutic use.

These results carry significant consequences for the incorporation of traditional medicine into contemporary healthcare. With the rising global popularity of herbal remedies, verifying their safety through recognized scientific methods such as the Draize test, promotes credibility and fosters broader acceptance. *Pachai Pakku Thailam*, according to the current findings, seems to be a

Table 3: Evaluation of Reactions (Draize’s Method) Control Group

	Rabbit Numbers			Average	Combined index
	1 M	2 M	3 M		
1 Hr					
Erythema Score	0	0	0	0.00	0.00
Edema Score	0	0	0	0.00	0.00
72 Hr					
Erythema Score	0	0	0	0.00	0.00
Edema Score	0	0	0	0.00	0.00

Table 4: Evaluation of Reactions (Draize’s Method) Test Group (Pachai Pakku Thailam)

	Rabbit Numbers			Average	Combined index
	1 M	2 M	3 M		
1 Hr					
Erythema Score	0	0	0	0.00	0.00
Edema Score	0	0	0	0.00	0.00
72 Hr					
Erythema Score	0	0	0	0.00	0.00
Edema Score	0	0	0	0.00	0.00

viable option for dermatological uses without irritation risk, advocating for its sustained application in traditional methods.

Conclusion

This study aimed to evaluate the potential for acute dermal irritation of *Pachai Pakku Thailam*, a traditional Siddha herbal oil, by employing the Draize method on rabbits. The formulation was topically applied to a shaved skin area valuations were conducted for erythema and edema at 1 hour and 72 hours after application. The results revealed no clear signs of skin irritation in any of the animals, and the computed Primary Irritation Index (PII) was 0.00, classifying the formulation as a non-irritant based on established toxicological standards. These results endorse the dermal safety of *Pachai Pakku Thailam* and confirm its conventional application in addressing diverse skin issues. The lack of irritation indicates that the formulation is well-accepted on topical application and can be safely employed as an herbal treatment. Nonetheless, additional research, encompassing prolonged exposure, sensitization, and human clinical trials, is advised to thoroughly determine its safety profile for broad clinical and commercial application.

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