

## EVALUATION OF SKIN IRRITATION POTENTIAL OF PRAPUNNATBIJADI LEPA: A PRECLINICAL SAFETY ASSESSMENT IN WISTAR RATS

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### ABSTRACT

**Background:** Prapunnatbijadi Lepa is a classical Ayurvedic formulation traditionally used in managing inflammatory and dermatological conditions. Before clinical application, scientific validation of its dermal safety is imperative to ensure non-toxicity and therapeutic reliability. **Objective:** This study aimed to evaluate the dermal irritation potential of Prapunnatbijadi Lepa in Wistar rats using a well-established preclinical in vivo model. **Materials and Methods:** Twelve healthy female Wistar rats were randomly allocated into two groups: Group I (Control) and Group II (Test, Prapunnatbijadi Lepa). The test formulation was applied topically for seven consecutive days after hair removal from the dorsal region. Dermal responses including erythema, oedema, and irritation index were monitored and scored as per OECD 404 guidelines.

Additional parameters included body weight changes, food consumption, clinical signs, necropsy findings, and organ weight analysis. **Results:** No dermal irritation, oedema, or systemic toxicity was observed in the test group throughout the study period. The irritation index remained zero in all animals. Statistically insignificant differences in body weight gain, food consumption, and organ weights were noted between the control and test groups. Gross necropsy and histopathological assessments showed no abnormalities. **Conclusion:** Prapunnatbijadi Lepa is devoid of dermal irritation potential and is safe for topical use in rats.

The findings reinforce the safety of traditional formulations when evaluated using modern toxicological protocols.

**KEYWORDS:** Prapunnatbijadi Lepa, dermal safety, OECD 404, skin irritation, Ayurveda, Wistar rats, toxicological evaluation.

## 1. INTRODUCTION

Topical preparations in Ayurvedic medicine, especially lepas (herbal pastes), have been traditionally employed for treating localized skin disorders, pain, inflammation, and musculoskeletal ailments. Prapunnatbijadi Lepa is one such formulation, believed to possess anti-inflammatory, antiseptic, and wound-healing properties owing to its composite herbal constituents. Despite its empirical use in clinical practice, a lack of scientific evidence on its dermal safety raises concerns about potential irritant reactions, especially with prolonged use or in sensitive populations.

Safety profiling of herbal formulations is imperative to align traditional knowledge with contemporary scientific and regulatory frameworks. The Organisation for Economic Co-operation and Development (OECD) Test Guideline No. 404, a globally accepted protocol for assessing acute dermal irritation/corrosion, provides a robust method for evaluating potential adverse effects upon dermal exposure.

This study was undertaken to investigate the skin irritation potential of Prapunnatbijadi Lepa using the OECD 404 model in healthy Wistar rats. The experiment also aimed to evaluate associated clinical, behavioral, gross pathological, and physiological effects to comprehensively establish its dermal safety.

## 2. MATERIALS

### 2.1 Test Item Details

- **Name:** Prapunnatbijadi Lepa
- **Form:** Herbal paste
- **Storage:** Room temperature under controlled laboratory conditions
- **Handling Precautions:** Standard biosafety and laboratory precautions were followed during preparation and application

### 2.2 Animal Details

- **Species:** Wistar Albino Rats

- **Sex:** Female
- **Age:** 6–8 weeks
- **Weight Range:**  $170 \pm 20$  g
- **Housing:** Polypropylene cages with stainless steel grid tops and corn cob bedding, three rats per cage
- **Environmental Conditions:** Temperature ( $22 \pm 3^\circ\text{C}$ ), relative humidity ( $50 \pm 5\%$ ), 12-hour light/dark cycle
- **Diet:** Standard pelleted laboratory feed
- **Water:** RO-purified ad libitum

### 3. METHODOLOGY

#### 3.1 Ethical Compliance

All experimental protocols were reviewed and approved by the Institutional Animal Ethics Committee (IAEC) under the Project Proposal No. SC/IAEC/2024/045. Guidelines of CPCSEA (Gazette of India, 1998) were strictly followed.

#### 3.2 Group Allocation

Group	No. of Animals	Treatment
I	6	Normal Control (no treatment)
II	6	Prapunnatbijadi Lepa application

#### 3.3 Procedure

Hair on the dorsal side of each rat was shaved 24 hours prior to the first application. A 2 mm thick layer of Prapunnatbijadi Lepa was applied once daily at the same time (10:30 AM) for 7 days on Group II animals. Control animals remained untreated. Post-application, all animals were observed daily for local dermal responses and behavioral changes.

#### 3.4 Skin Irritation Scoring

Following OECD 404, skin reactions were scored as:

- **Erythema & Eschar Formation:** 0 (none) to 4 (severe with eschar)
- **Oedema Formation:** 0 (none) to 4 (severe, raised  $>1$  mm)

An Irritation Index was calculated daily based on average scores.

#### 3.5 Observational Parameters

- Dermal responses (erythema, oedema)
- Body weight (Day 1, 4, 7)

- Food consumption
- Clinical signs of toxicity
- Gross necropsy
- Absolute and relative organ weights

#### 4. OBSERVATIONS AND RESULTS

##### 4.1 Body Weight Monitoring

Both groups exhibited progressive weight gain across the 7-day study period.

Day	Control (g)	Test Group (g)
1	167.02 ± 8.47	166.85 ± 8.59
4	178.87 ± 7.65	178.45 ± 9.68
7	190.20 ± 6.67	190.77 ± 10.45

##### 4.2 Food Consumption

Slight variations were seen but remained statistically non-significant.

Day	Control (g/day)	Test Group (g/day)
1	13.10 ± 3.87	12.73 ± 5.56
4	12.88 ± 3.70	11.68 ± 3.75
7	12.77 ± 4.57	12.43 ± 3.58

##### 4.3 Skin Irritation Scores

Erythema and oedema scores remained zero for all animals throughout the study.

##### 4.4 Irritation Index

Irritation Index for both groups on all days was 0.00 ± 0.00.

##### 4.5 Clinical Observations

No clinical abnormalities (e.g., salivation, lacrimation, lethargy, gait/posture changes) were recorded in either group.

##### 4.6 Necropsy Findings

Gross necropsy revealed no abnormalities in external or internal organs.

##### 4.7 Organ Weights

Relative organ weights (% body weight) did not differ significantly.

Organ	Control Group (%)	Test Group (%)
Liver	4.02 ± 0.23	3.94 ± 0.18
Lung	0.74 ± 0.06	0.69 ± 0.06
Heart	0.39 ± 0.06	0.36 ± 0.05
Spleen	0.50 ± 0.08	0.53 ± 0.09

## 5. DISCUSSION

The study establishes the dermal safety of Prapunnatbijadi Lepa when applied topically in an animal model. The formulation did not elicit erythema, oedema, or any observable toxicological effects during the 7-day period. Furthermore, normal body weight gain and food consumption patterns reinforce the absence of systemic toxicity.

The OECD 404 guideline is a globally acknowledged framework for evaluating acute dermal reactions, and its implementation in this study adds robustness and comparability to the results. In line with previous investigations on herbal lepa formulations, our results support the benign nature of this traditionally used preparation.

Absence of abnormal clinical signs, necropsy findings, and organ weight deviations provide further evidence that Prapunnatbijadi Lepa is safe for external use. Importantly, such data form the foundation for designing human safety trials.

## 6. CONCLUSION

Under the tested conditions, Prapunnatbijadi Lepa was found to be non-irritant and safe for dermal application in Wistar rats. It meets the standard toxicological parameters set by OECD 404. This finding scientifically substantiates its traditional application in Ayurveda and supports further clinical research.

## 7. Future Scope

- **Extended Toxicity Profiling:** Sub-chronic dermal toxicity and sensitization studies
- **Pharmacological Evaluation:** Assessing therapeutic efficacy in inflammatory and infectious dermatoses
- **Histopathological Analysis:** Microscopic tissue response to long-term application
- **Clinical Trials:** Phase I safety trials in healthy human volunteers

## REFERENCES

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