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## **Acute and sub acute toxicity study of Herbo mineral formulation Palagarai Chunnam**

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### **Abstract**

The Herbo mineral formulation Palagarai chunnam (PC) has been used for treat many diseases like Anemia, Dropsy, Dysmenorrhea, female infertility. The aim of the present study was to evaluate the in-vivo toxicity of PC. The acute and subacute oral toxicity of PC was evaluated in Wister albino rats. As a obligatory steps were taken to evaluate safety and efficacy of trial drug PC. According to OECD guidelines, acute toxicity single dose of 5mg, 50mg, 300mg and 2000 mg of PC were administered, and monitor for 14 days. A single dose of 2000 mg/kg did not produce treatment related signs of toxicity or mortality in any of the animals tested during the 14-day observation period. Therefore, the LD 50 of this plant was estimated to be more than 2000 mg/kg. Sub-acute toxicity studies were carried out in four groups of 10 animals (5 male & 5 female). The test drug PC administered to rats for 28 days. After the study period the detailed hematological, biochemical, Histopathological evaluation of different organs was performed in all animals. Histopathological analysis revealed that the liver, lung, kidney, heart of treated groups did not show any signs of toxicity. Analyses of these results with the information of signs, behavior, and health monitoring could lead to the conclusion that Acute and sub-acute oral administration of PC for 28 days does not cause toxicity.

**Keywords:** Palagarai chunnam, Acute and sub-acute, Rats

### **1. Introduction**

Medicine as everyone knows is not merely a science but an art as well. The Siddhars, through enumeration, implied that the herbs and minerals are used as 'special foods', serving to eliminate excesses and to strengthen deficiencies. They have a powerful nutritive impact on a weakened body and their primary action is to stimulate particular organic functions, thereby acting more effectively than normal food. Siddha medicine uses an extensive pharmacopoeia that includes herbal, animal, mineral and metallic preparations<sup>(1)</sup>. The system has developed a rich and unique treasure

of drug knowledge in which use of various types of herbs, metals, minerals and animal products is very much advocated. These writings, preserved in codified poems and oral transmission, are an accumulation of knowledge about the pharmacology and ecology of herbal, animal and mineral medicines. This is not only a system of medicine but also a part of culture of the society and it employs a holistic approach in its treatment methodology and it has made enormous contribution to the healthcare of the people. This system also deals with the concept of salvation in life<sup>(2)</sup>.

The prevalence of female infertility Number of married women aged 15-44 that are infertile is 1.0 million. Number of women aged 15-44 who have ever used infertility services: 6.9 million. Globally, anaemia affects 1.62 billion people (95% CI: 1.50–1.74 billion), which corresponds to 24.8% of the population (95% CI: 22.9–26.7%). The highest prevalence is in preschool-age children (47.4%, 95% CI: 45.7–49.1), and the lowest prevalence is in men (12.7%, 95% CI: 8.6–16.9%)<sup>(3)</sup>.

The prevalence of dysmenorrhea in adolescent girls was found to be 79.67%. However, the population group with the greatest number of individuals affected is non-pregnant women (468.4 million, 95% CI: 446.2–490.6). Because of the increased prevalence there is an emergence need of an effective drug for the management of female infertility, Dysmenorrhea, anaemia and other chronic diseases<sup>(4)</sup>.

*Palagarai chunnam* is one of the traditional Siddha formulation which is indicated as a best drug for Female Infertility, Dysmenorrhea, Anaemia, Dropsy in Siddha text *Siddha maruthuva nool thirattu - Anubhava Siddha Vaithiya Muraigal*. Scientific validation of this formulation *Palagarai chunnam* have to be studied and the safety of the drug have to be ensured.

## 2. Materials and Methods

### 2.1 Authentication:

Palagarai were procured from authenticate source of Raw Drug market at Chennai. Identification and



authentication done on Marine Biology Regional Centre, Chennai. The Herbal drug Citrus limon (Lemon) and Ilaikkalli (*Euphorbia nerifolia* Linn.) identified and authenticated by Assistant Professor, Department of Medicinal Botany, National Institute of Siddha, Chennai-47.

### 2.2 Preparation of palagarai chunnam:

#### 2.2.1 Purification of palagarai:

1. Palagarai (*Cypraea moneta*) - 100gm
2. Elumichai Pazha Saaru (*Citrus limon*) - Q.s

Take the above mentioned quantity of *Palagarai* kept immersed in juice of lemon up to 24 hours<sup>(5)</sup>. Then wash those *Palagarai* with pure water and then dried in sun light.

#### 2.2.2 Method of preparation:

Take the above mentioned quantity of *Palagarai* (*Cypraea moneta*) kept immersed in juice of lemon upto 24 hours. Then wash those *Palagarai* by using water. Those purified *Palagarai* have to be kept inside the 200g of Grinded Ilaikkalli (*Euphorbia nerifolia* Linn.) Leaves and it is covered by 5 layers of mud sealed cloth and dried well. Then it will be subjected into *putam* by using 30 cow dung cakes<sup>(6)</sup>. After incineration remove the mud sealed cloth and collect the *chunnam*. Then it will be grind and have to be kept in air tight container.



### 2.3 Toxicity studies of palagarai chunnam

Preclinical safety evaluation *Palagarai chunnam* with acute and subacute toxicity study carried out as followed. Principles of laboratory animal care were followed and the Institutional Animal Ethical

Committee approved the use of animals and the study design. Institutional Animal Ethics Committee approval number: **NIS/IAEC/II/08/2016** dated 29.9.2016 for acute toxicity study and repeated dose 28-day oral toxicity study.

### 2.3.1 Acute toxicity study of palagarai chunnam

#### Experimental Animals:

Species	:	Wistar Albino Rats
Sex	:	Female
Age/weight	:	6 weeks/140-160gm b.wt
Acclimatization Period	:	7 days prior to dosing
Housing	:	Polypropylene cages bedding with husk
Husbandry	:	12-h light/12-h dark cycle/
Room temperature	:	22°C ± 3°C and
Relative humidity	:	30–70
Feed and Water	:	Rodent pelleted feed RO purified water
Identification	:	Animals will be kept in Polypropylene cages and marked

#### Experimentation Details of Acute Toxicity Study:

Groups/Treatment regimen	:	Grouped by randomization
Test Guideline	:	OECD-423
Duration of the exposure to test drug	:	Once single dose
No of Animals	:	3 Female/ group
Control group	:	Adjuvant (Milk)
Test groups	:	Palagarai chunnam 300,2000 mg/kg b.wt

The Female Albino Rats of weighing 150-200g were obtained from authorized animal breeders of the animal laboratory in TANUVAS, Madhavaram, and Chennai and stocked in the animal house at National Institute of Siddha, Chennai.

Animals were housed in a cage at 22°C ±3°C and relative humidity 30–70% and have free access to standard rat pellet diet. The animals are divided into three groups (Group I, II & III). Each group contains 3 female Wistar albino rats. Group I served as a control and treated with milk.

The remaining two groups were treated with 300mg/kg.b.wt and 2000mg/kg.b.wt dosage of Palagarai chunnam by oral route after 12 hrs fasting with free from water. After drug administration behavioral parameters are monitored for the first 4 hours continuously (1/2 hr, 1hr, 2 hr, 3 hr,4hr) and noted. The animals that die within this period will be subjected to necropsy. Remaining animals will be weighed and sacrificed under the injection of Pentothal Sodium on the 15<sup>th</sup> day of the Study period. The toxicological effect was assessed on the basis of mortality.

#### Route of administration

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

#### Administration of Dose

The animals were fasted (only food was withheld) for 12hrs and weighed prior to dosing. Three animals were used for each step. A single dose of the solution (300,2000mg/kg/b.wt) was consecutively administered by oral gavage using intubation cannula. The food was withheld for another 4hrs after dosing of the drug. Observations were made and recorded systematically and continuously observed after the substance administration as per the guidelines<sup>(7)</sup>.

- ½ hour, 1 hour, 2 hours, 4 hours and up to 24 hours observation
- All rats were observed twice daily for 14 days
- Body weight were Calculated weekly once
- Feed & water intake were Calculated daily

#### Cage side observation

The animals were monitored for behavioral parameters like Alertness, Aggressiveness, piloerection, Grooming, Gripping, Touch Response, Motor Activity, Tremors, Convulsions, Muscle Spasm, Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmos, Diarrhea, Writhing, Respiration, Mortality.

**Gross necropsy**

At the end of the 14<sup>th</sup> day, all the animals were sacrificed by using the injection of Pentothal sodium. Gross necropsy includes examinations of the external

surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Brain, eye, lungs, heart, spleen, liver, kidneys, adrenals, uterus, of all animals.

**Table.1 Behavioral Signs of Acute Toxicity Study**

No	Dose Mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	Control	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2.	300	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3.	2000	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

**+ Presence of activity / - Absence of activity**

1. Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15. Lacrimation 16. Exophthalmos 17. Diarrhoea 18. Writhing 19. Dyspnoea 20. Mortality

There was no mortality observed after dosing of **Palagarai chunnam** upto 2000mg/kg body weight. This indicates that LD50 of **Palagarai chunnam** is more than 2000mg/kg b.wt. There were no changes in skin and fur, eyes and mucous membranes of all animals. The eating, drinking habit, sleep pattern,

locomotion were normal in all animals and no changes in body weight as compared to control group. At the end of the 14<sup>th</sup> day, necropsy was performed and there was no abnormality seen in test groups as compared to control group during the examination.

**2.3.2. 28-Day oral toxicity study of palagarai chunnam****Experimental Animals:**

Species	:	Wistar Albino Rats
Sex	:	Male and Female
Age/weight at start of test	:	6 weeks/140-160g b.wt
Acclimatization Period	:	7 days prior to dosing
Housing	:	Polypropylene cages bedding with husk
Husbandry	:	12-h light/12-h dark cycle/Room temperature 22°C ± 3°C and Relative humidity 30–70%
Feed and Water	:	Rodent pelleted feed RO purified water ad libitum
Identification	:	Animals will be kept in Polypropylene cages and numbered

**Experimentation Details of Repeated dose 28 days Toxicity Study:**

Groups/Treatment regimen	:	Grouped by randomization
Test Guideline	:	OECD-407
Length of exposure to test substance	:	28 days
No of Animals	:	5 Female+5 Male / group
Control	:	Adjuvant (Milk)
Test group	:	Low dose, mid dose, High dose

The animals weighted in range of 150-200 gm. of 20 male and 20 female Wistar albino rats are used for 28 days repeated oral toxicity study. The animals are divided into four groups. Each group contains 10

animals (5 female and 5 Male). The first group treated as control and second, third, fourth groups were treated with **Group 1. Control, Group 2. Low dose, Group 3. Mid dose and Group 4 High dose.**

Above mentioned dose of palagarai Chunnam mixed with milk for 28 days respectively after 12 hrs. of fasting with free from water. The low dose, mid dose and high dose of test drug will be calculated from human therapeutic dose based on surface area by using the conversion table of Paget and Barnes (1964). The control animals were administered with milk as adjuvant.

The administration was given by oral, once daily for 28 consecutive days. The animals were observed the behavioral parameters for the study period. Body weight of the animal was being monitored at weekly intervals. Food & water intake were Calculated daily. All the animals were sacrificed at the end of the study (29<sup>th</sup> day) by using the intra peritoneal injection of Pentothal Sodium as prescribed dose level. Blood was collected from the anesthetized animals from the Abdominal aorta for the following investigations like Hematology and Biochemical analysis. Gross pathological changes were monitored in all the organs then the vital organs were preserved and subjected to Histopathological examination<sup>(8)</sup>.

#### Observations:

Experimental animals were kept under observation throughout the course of study for the following

- All rats were observed twice daily for 28 days
- Body weight were Calculated weekly once
- Feed & water intake were Calculated daily

#### a. Cage side observation

The animals were monitored for behavioral parameters like, Alertness, Aggressiveness, piloerection, Grooming, Gripping, Touch Response, Motor Activity, Tremors, Convulsions, Muscle Spasm, Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmos, Diarrhea, Writhing, Respiration, Mortality.

#### b. Laboratory Investigations:

On the 29th day, the animals were fasted overnight, then anesthetized to collect blood samples from the abdominal aorta in two tubes: one with EDTA for hematological parameters, another one without any anticoagulant and was centrifuged at 4000 rpm at 4°C for 10 minutes to obtain the serum for biochemical parameters.

#### c. Hematological Investigations:

Blood samples of control and experimental rats were analyzed for haemoglobin (Hb), total red blood

corpuscles (RBC), white blood corpuscles (WBC) count, Platelet, Mean corpuscular volume (MCV), Mean corpuscular hemoglobin (MCH), were calculated by auto analyzer.

#### d. Biochemical Investigations:

Serum samples of control and experimental animals were analyzed for, Bilirubin, BUN, Creatinine, Triglyceride, Total Cholesterol, HDL, LDL, VLDL, using standard methods. Activities of glutamate oxaloacetate transaminase/Aspartate aminotransferase (GOT/AST), glutamate pyruvate transaminase/ Alanine aminotransferase (GPT/ALT) were estimated as per the colorimetric procedure.

#### e. Necropsy:

All the animals were sacrificed on the 29th day and satellite group were sacrificed on after 14 days. Gross necropsy includes examinations of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Brain, eye, lungs, heart, spleen, liver, kidneys, adrenals, sex organs, of all animals were recorded.

#### f. Histopathology:

The organs included liver, kidneys, spleen, brain, heart, lungs and stomach of the animals were preserved, and they were subjected to Histopathological examination. Histopathological investigation of the vital organs was done. The organ pieces (3-5µm thick) of all the animals (low, mid, high and control) were preserved and fixed in 10% formalin for 24 hrs.

Samples were dehydrated in an auto technic and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" molds. It was followed by microtome and the slides were Prepared then stained with Haematoxylin-eosin.

#### g. Statistical analysis:

Findings such as body weight changes, food consumption, water intake, and hematology and biochemical analysis were subjected to One-way ANOVA Dunnet's test using a computer software program followed by **D Graph Pad Instat-3**.

### 3. Results

**Table 2: Food (g/day) intake of albino rats exposed to Palagarai chunnam**

Dose (mg/kg/ day)	1 <sup>st</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	21 <sup>st</sup> day	28 <sup>th</sup> day
Control	10.25±0.16	11.25±0.18	12.5±0.28	12.8±0.25	13.15±0.18
LD	12.8±0.21**	13.8±0.21**	13.95±0.38*	14.65±0.38**	16.3±0.32**
MD	12.45±0.16**	13.5±0.45**	14.8±0.54**	16.8±0.54*	16.95±0.15**
HD	12.15±0.158**	14.95±0.17**	15.15±1.25**	16.95±0.71*	18.65±0.25**

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates \*P<0.05, \*\*P<0.01.

There was significant difference occurs in test groups compared with control group. but they are within physiological limit.

**Table 3 Water (ml/day) intake of albino rats exposed to Palagarai chunnam**

Dose (mg/kg/day)	1 <sup>st</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	21 <sup>st</sup> day	28 <sup>th</sup> day
Control	16.45±0.35	21.65±0.45	23.56±0.38	22.38±0.25	24.95±0.95
LD	16.95±0.25	19.84±0.35**	22.65±0.15*	22.15±0.18	26.35±0.25**
MD	17.15±0.35	21.65±0.35	23.95±0.18	24.35±0.28*	28.95±0.28**
HD	18.36±0.46	21.45±0.24	22.65±0.28*	23.55±0.38**	28.83±0.24**

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates \*P<0.05, \*\*P<0.01

**Table 4 Body weight (g) changes of albino rats (male) exposed to Palagarai chunnam**

Dose Mg/kg	1 <sup>st</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	21 <sup>st</sup> day	28 <sup>th</sup> day
Control	155±12.70	161±13.50	172±15.20	180.66±18.45	194±19.20
LD	158.2±10.05	168.3±14.07	178.45±16.52	190.33±18.71	205.66±18.45
MD	178±11.50**	188±12.51**	200.23±12.36*	210.23±15.6*	221.33±20.64
HD	181.66±7.50*	189.33±8.02*	199±9.21	208±8.29*	238.33±10.50**

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates \*P<0.05, \*\*P<0.01

Body weight of both control and test dose group revealed normal body weight throughout the study.

**Table:5 Body weight (g) changes of albino rats (female) exposed to Palagarai chunnam**

Dose (mg/kg/day)	1 <sup>st</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	21 <sup>st</sup> day	28 <sup>th</sup> day
Control	148±4.55	154.66±4.66	164±5.35	174.33±8.08	186.33±6.78
LD	143.23±5.14	152.66±6.09	165.66±8.09	176±8.18	192.33±6.02
MD	147.66±6.09	157.35±6.68	169.56±6.85	181.65±5.15	194.33±8.72
HD	152.66±5.85	159.66±6.80	164.15±6.25	177±5.55	195.35±7.15

Body weight of both control and test dose group revealed normal body weight throughout the study.

**Table: 6 Effect of Palagarai chunnam on Hematological Parameters**

	Control	LD	MD	HD
RBC ( $\times 10^6/\mu\text{l}$ )	5.68±0.35	6.02±0.52*	6.09±0.57	6.18±0.91
WBC ( $\times 10^3/\mu\text{l}$ )	9.6±1.42	8.37±1.39	8.5±2.85	7.78±2.16
PLT ( $\times 10^3/\mu\text{l}$ )	768.5±89.14	685.5±142.54	583.5±94.52**	765.7±96.55
HGB (g/dl)	11.64±1.69	12.16±1.37	13.2±1.23	13.8±1.59**
MCH (pg)	18.39±2.47	18.87±1.71	20.97±0.87**	22.41±1.46**
MCV (fl)	56.98±2.73	59.81±3.81	58.86±4.36	59.7±5.76
Neutrophils $10^3/\text{mm}^3$	2±0.52	1.91±0.42	1.41±0.33**	1.52±0.23*
Eosinophil's (%)	1.58±0.22	1.41±0.24	1.44±0.19	1.54±0.29
Basophils (%)	0.2±0.42	0.2±0.42	0.2±0.42	0.1±0.32
Lymph (%)	68.14±5.41	83.42±7.17**	79.07±9.06**	71.97±7.94
Mon (%)	3.82±0.94	2.59±0.94	4.13±0.79	3.76±1.02

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates \*P<0.05,\*\*P<0.01

**Table:7 Effect of Palagarai chunnam on biochemical parameters-Lipid profile**

	Control	LD	MD	HD
<b>Total cholesterol (mg/dl)</b>	109.26±15.22	113.93±10.09	129.17±8.41**	127.4±11.56**
<b>HDL (mg/dl)</b>	60±4.74	58.2±8.26	61.1±8.79	58.6±7.95
<b>LDL (mg/dl)</b>	43.6±13.21	37.2±9	49.3±7.01	48.6±11.14
<b>VLDL (mg/dl)</b>	12.25±1.34	17.2±4.57**	15.04±2.54	17.66±4.11**
<b>TGL (mg/dl)</b>	50±4.69	41±10.39	37.9±7.99**	36.8±9.93**

**Table: 8 Effect of Palagarai chunnam on Renal Parameters**

	Control	LD	MD	HD
<b>BUN (mg/dl)</b>	12.5±1.58	15.1±2.47*	15.5±2.17**	14.7±2.16
<b>Serum Creatinine (mg/dl)</b>	0.57±0.15	0.63±0.13	0.56±0.18	0.7±0.24

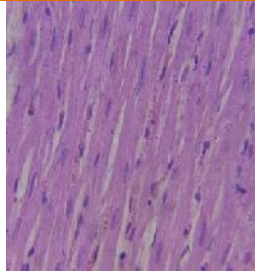
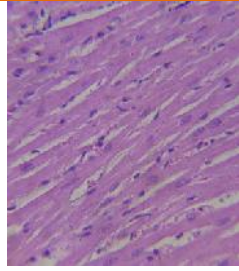
Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates \*P<0.05, \*\*P<0.01

**Table: 9 Effect of Palagarai chunnam on Hepatic Parameters**

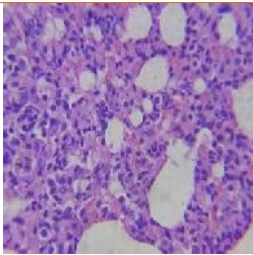
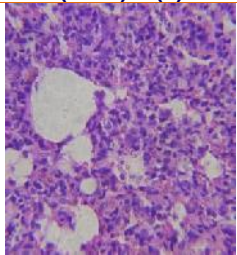
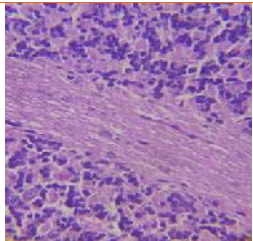
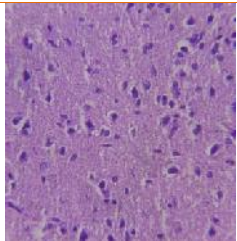
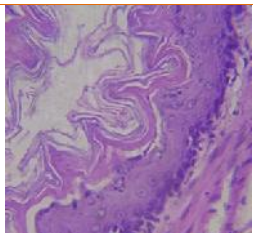
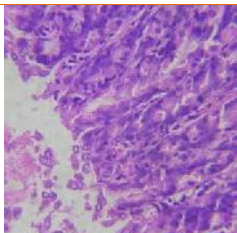
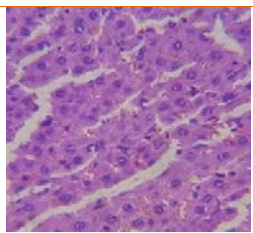
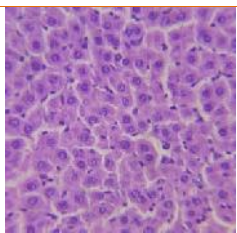
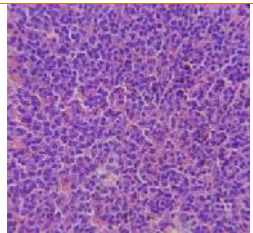
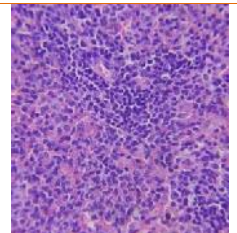
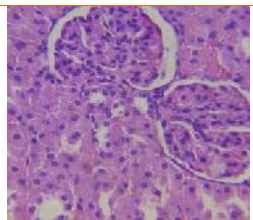
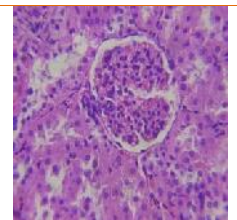
	CONTROL	LD	MD	HD
<b>Total Bilirubin (mg/dl)</b>	0.32±0.12	0.37±0.11	0.34±0.15	0.53±0.38
<b>SGOT (IU/ml)</b>	89±10.82	92.9±17.95	97.4±32.3	97.5±16.15
<b>SGPT (IU/ml)</b>	26.4±7.27	30.8±7.10	36.8±6.97**	36.8±7.05**

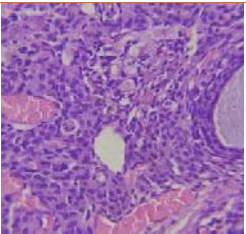
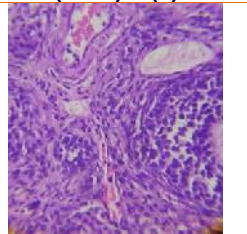
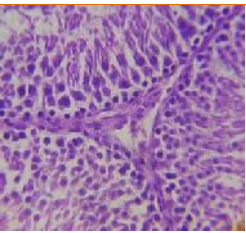
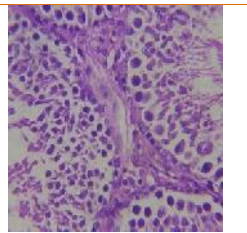
Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates \*P<0.05, \*\*P<0.01

**Table 10 : Histopathology of Vital organs (Albino Rats)**

ORGANS	LOW DOSE	HIGH DOSE	RESULTS
HEART			No abnormality



LUNGS			No abnormality
BRAIN			No abnormality
STOMACH			No abnormality
LIVER			No abnormality
SPLEEN			No abnormality
KIDNEY			No abnormality

UTERUS			No abnormality
TESTIS			No abnormality

#### 4. Discussion

**In Acute toxicity study** (Table -1), carried out as per OECD guideline 423, there was no treatment-related death or signs of toxicity developed in albino rats at dosage levels of 300mg and 2000mg/kg body weight throughout the study period. Further, no gross pathological changes have been seen in the internal organs of both control and treated groups. This study reveals the safety of the drug. To confirm the safety of Palagarai chunnam, **28 days Repeated Oral Toxicity Study** was also carried out as per OECD test guideline 407. The animals were grouped and treated with different doses in study period as per guidelines. After 28 days blood collection done for animals of all groups. All the animals were euthanized for gross pathological examinations of all major internal organs.

The blood samples were sent to a lab for hematological and biochemical analysis. The organs were weighed and preserved in 10% buffered formalin solution before sending for Histopathological study. All the reports were statistically evaluated.

Palagarai chunnam Substantial difference in Food and water intake the test group animals were observed when compared with control group during the study period (Table 2, 3) but they are within physiological limit, and this study exposes that it does not undesirably affect the basic metabolic processes of the experimental animals. In Hematological parameters, it had been observed that hemoglobin level was elevated after the administration of palagarai chunnam at the high dose level when it compared to control group animal (Table 6). But the Hb level was gradually increased in test group compared to the control group but within normal range. In test groups there was significant changes present in Lipid profile, when compared with the control group. At the values

were normal biological limits. (Table 7). The Biochemical parameters like Renal and hepatic parameters has significant changes but within normal range. (Table 8,9). The Histopathological study, organs such as brain, heart, kidney, liver, lungs, spleen and stomach were taken. In organs of Control and test group, no abnormality was detected. There's no pathological changes occur in all group of animals during the study period.


#### 5. Conclusion

In vivo toxicity studies indicate that there was no mortality and signs of toxicity observed for acute oral administration of test drug till the dose 2000 mg/kg b.wt in the recommended manner. In 28 days repeated oral toxicity study hematological and biochemical parameters are normal limits and no significant abnormality present in internal organs. Oral administration of the test drug **Palagarai chunnam** to albino rats at 10 times higher than recommended dose also caused no toxicological effects. Acute and subacute toxicity studies of test drug in the study clearly showed the non-toxic nature and high safety profile of Palagarai chunnam in rodents.

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