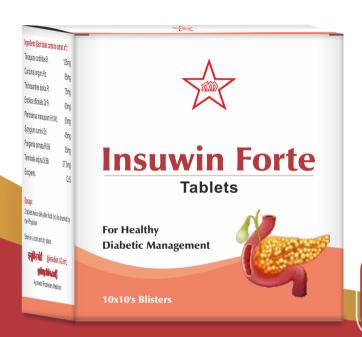


SKM VAIDHYA AMIRTHAM

News Letter of SKM in Siddha, Ayurveda and Unani

 JULY - SEPTEMBER 2023



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Skipping dinner once a week is recommended. As it helps in - clarity of sense organs, excretion of waste from the body, lightness, hunger, thirst, belching, enthusiasm and reduction in tiredness.



Articles are invited in SIddha, Ayurveda and Unani fields about clinical experience, rare medicinal preparations, successful treatments, Herbal informations and AYUSH Foods for our "SKM Vaidhya Amirtham" News letter which has around 10000 copies

Please send your Articles/Suggestions to: SKM Center for Ayush System Research and Education

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Assessment of Concentrations of Heavy Metals in patients with prolonged intake of certain Herbo-mineral Siddha drugs- observational study.

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INTRODUCTION:

Siddha, one of the Indian systems of medicine, owes its origin to medicinal treatment and practices of a class of Tamil sages called siddhars the holy immortals. Siddha medicine system unlike other systems is a complex system of science in so far as it has included in the works of medicine, alchemy, yoga, rejuvenation, Varma, etc., with a view to hoist them in the long run to attain the level of eternity. The siddha system of medicine is a living science system which has practiced through many centuries.¹

This traditional Indian medicine is used widely throughout the Indian subcontinent and among South Asian ethnic communities worldwide. Siddha medicines are also increasingly popular in many countries and available from markets, practitioners, health food stores, and e-commerce platforms. The source of pharmaceutical preparations in siddha system comprises medicinal herbs, metals, minerals and animal things. Some of Siddha pharmacopoeia employs heavy minerals and metals, such as lead, arsenic and mercury.

Some of the mineral and metallic preoperational drugs indicated for Skin diseases, vadha diseases, purifies blood, strengthen nerve plexus, prevent senility, chronic ailments and increases life span. And it was quoted in many siddha books like Siddha Vaidya thirattu, Athmaratchamirtham, Agasthyar Chendooram, Agasthyar Vaidya kavyam and The Siddha pharmacopeia of India etc.

The issues related to lack of scientific evidence about the efficacy and safety of herbo mineral remedies remains unresolved. A preclinical toxicity study is mandatory in determining a safety dose for human trial. Prior to the initiation of the human trial the safety of the drug is to be proved. Our clinical experience with several siddha mineral and metallic drugs suggested to give greater effects on the blood system and did not explode any clinical intoxication. To explore this hypothesis, we analyzed the hematopoietic manifestations among siddha treatment through patients with long term medications. Modern science and developed countries claims the heavy metallic traditional drugs leads to toxicity of the patients. In order to prove the safety of the patients with long term medications of siddha herbo-mineral drugs.²⁻⁸

This observational study to obtain preliminary evidence on the safety of the patients with prolonged intake of siddha herbomineral drugs. Investigation of heavy metals in the patients' serum among users of siddha medicine.

MATERIALS AND METHODS:

We retrospectively observed adult patients (≥18 years old) who are consuming the siddha mineral and metallic drug therapies in longer period. They included: Patients with chronic disease and treatment with herbo-metallic siddha drugs more than one year with different sex& age groups. And Patients who are not under the treatment in any other system of medicine. Also they are not advised of any new functional, nutritional foods. Patients not to exposure of any industrial pollutions and Odors.

30 Patients with various chronic disease who were taking the heavy Metallic Siddha drugs in different age groups at SKM chikitchalaya, Erode, Tamil Nadu, India. Clinical assessment with subjective and blood analysis of heavy metals through AES (Atomic emission spectrometry) and serum renal & Liver function Tests.

Blood screening

The clinic advised all of their patients to stop use of siddha mineral and metallic drugs obtained through their clinic until results of an analysis for metals for their blood were available. Individuals were invited to participate in blood heavy metal screening and asked to document all medicinal usage, sources of these substances, and medical symptoms. Blood heavy metal screening testing was performed predominantly by the vimta Laboratory, and blood mercury testing was performed by SKM Medical Laboratory.

Blood analysis of heavy metals through AES (Atomic emission spectrometry) and all cases after careful examinations were investigated before testing and documented accordingly. Patients were instructed to attend the clinic for the assessment and give the blood samples at the SKM clinical laboratory.



Outcome Measures: Measured patient's history of high Blood Pressure, Tachycardia, Arrhythmia, Abnormal heart sounds, dark skin, Renal symptoms, nerves disorders, Sensory change, Tingling, Inflammation nerves, chronic headache, Vertigo, fatigue, Weight loss, Tremors, Anxiety, Lack of concentration, Seizures, Hallucination, Metallic taste, Anorexia, visual disturbances and values of mercury, lead and Arsenic in blood.

Blood metal concentration was measured based on SOP No:26/ICP-AES/10 inductively coupled plasma – Atomic emission spectrometry (ICS-IES) technique. The aqueous acidified sample is aspirated in to the plasma generated using Argon gas. The specific analyte ions are detected by charged couple device. The concentration of the analyte is compared with the Values of standards obtained on a linearity curve reported in the units. We defined heavy metal values according to the WHO standard below the generally accepted the both limits of normal ranges as lead 20-250 μ g/L, Mercury 0.6-59 μ g/L and Arsenic 2-23 μ g/L in serum samples as shown in Table. 1

Metals In Blood	Normal Range	Chronic Toxic Level	Methods
Mercury	0.6-59 μg/L	66& above	ICP-AES
Lead	20-250 μ g/L	250& above	ICP-AES
Arsenic	2-23 μ g/L	100-500	ICP-AES

Table.1. Normal ranges of serum heavy metal.

Study procedure

The participants who fulfill the inclusion criteria were registered and examined for the baseline characteristic wherein demographic profile, medical history, data from general and systemic examinations were recorded at one time and outcomes were analyzed. This retrospective study was exempted from IRB approval because it was part of a public health response.

Statistical analyses

Patients' characteristics were described using percentages for categorical variables and means \pm SD for quantitative variables.

RESULTS:

Forty individuals participated in the baseline screening for heavy metal analysis. Among them, 10 patients were excluded because they were taking modern medicine from other hospitals. 30 screened individuals eligible for study. The mean age of the study group was 42.96 ± 12.99 years; the mean treatment period of the individual was 5.2 ± 1.45 years as presented in the Table.2. No one affected with the symptoms related to the metallic intoxication and documented accordingly.

The concentrations of metals in the serum samples of the patients with their descriptive statistics are presented in Table 2. Mercury levels in serum samples from the patients are ranging from 0.5 μ g/L to 55.6 μ g/L with a mean value of (p < 0.001) as 15.39 μ g/L (stdv 13.83), Lead in serum samples from the patients are ranging from 8.0 μ g/L to 140 μ g/L with a mean value of 64.75 μ g/L (stdv 40.083) and Arsenic levels in serum samples from the patients are ranging from 1.0 μ g/L to 22.8 μ g/L with a mean value of 7.48 μ g/L (stdv 7.75).

	N	Minimum	Maximu m	Mean	Std. Deviation
AGE	30	23 Year	67 Year	42.9667	12.99730
TREATMENT PERIOD	30	1 Year	7 Year	5.2333	1.45468
MERCURY	25	.30	55.60	15.3848	13.83023
LEAD	19	8.40	140.00	64.7553	40.08313
ARSENIC	17	1.00	22.80	7.4829	7.75418

The total Bilirubin levels in serum samples from the patients are ranging from 0.6-1.82 mg/dl, direct bilirubin levels in serum samples from the patients are ranging from 0.1-0.76 mg/dl, Indirect bilirubin levels in serum samples from the patients are ranging from 0.14-1.06 mg/dl and SGOT and SGPT levels in serum samples from the patients are ranging from 10-25 mg/dl are presented in Table.3.



TEST	T. Bilurubin IN mg/dl	D. Bilurubin INmg/dl	ID. Bilurubin IN mg/dl	SGOT IN UNITS	SGPT IN UNITS
VALUES	0.6-1.82	0.1-0.76	0.14-1.06	10-25	10-25
NORMAL RANGE	0.1-1.8	0.0-0.6	0.3-1.0	8-50	5-35

Table.3. Liver function test

Based on the renal function test report as shown in table.4 the urea levels in serum samples from the patients are ranging from 14.2-30 mg/dl and urea levels in serum samples from the patients are ranging from 0.6-1.7 mg/dl.

Table.5 represented the patient's disease condition and their heavy mineral and metallic medication with its mineral and metal

TEST	SERUM UREA IN mg/dl	SERUM CREATININE IN mg/dl	SERUM URIC ACID IN mmol/l	SERUM Na IN mmol/l	SERUM K IN mg/dl	SERUM ALBUMIN IN mg/dl	SERUM GLOBULN IN mg/dl
VALUES	14.2-30	0.6-1.7	3.4-6.2	130-144	4.3-4.9	3.4-5.4	1.7-5.7
NORM AL RANGE	15-45	0.6-1.3	3.5-7.2	136-145	3.5-5.1	3.8 – 5.4	1.8 - 3.6

Table.4. Renal function test

Disease	No. of Cases	Medicine	Heavy metal Ingredients
Diabetes	13	Mega Narayana Chenduram	Mercury, Arsenic
Bronchial asthma	4	Poorna chandrothya Chenduram & Kasthuri karuppu	Mercury, Arsenic
Leucoderma	4	Navapasana Chenduram	Mercury, Arsenic
Psoriasis	3	Navapasana Chenduram & Nagavanga Chenduram	Mercury Lead & Arsenic
Eczema	1	Rasagandhi mezhugu & Sivanar amirtham	Mercury
Arthritis	3	Nagavanga Chenduram & Chandamarutha Chenduram	Mercury Lead & Arsenic
Sinusitis	2	Poornachandrothaya Chenduram & Arumuga Chenduram	Mercury

Table.5. Patient's diagnosis and their consumed drugs

DISCUSSION:

ingredients among 30 participants.

Lead, Arsenic and mercury are toxic to multiple organ systems and can have a variety of presentations. Abnormal heart sounds, dark skin, Renal symptoms, nerves disorders, Sensory change, Tingling, Inflammation nerves, chronic headache, Vertigo, fatigue, Weight loss, Tremors, Anxiety, Lack of concentration, Seizures, Hallucination, Metallic taste, Anorexia, visual disturbances may also be a systemic symptom. The diagnosis is made with these symptoms is not given the exact diagnosis of the intoxicative patients.

Also serum heavy metallic concentration is the main diagnostic point for rule out the diagnosis. In this study no one can affected with the above said symptoms according to the current observation.

Siddha heavy metallic drug intoxication and its significant hematopoietic toxicity have important clinical and public health implications. Since the completion of our study there is no one of siddha heavy metallic drug poisoning have been reported.

Herbo mineral siddha drugs are safe to use in the management of many chronic diseases. And the drugs are nontoxic in the use of various chronic disease for the prolonged (More than one year) treatment. Considerable dose in the use of the siddha mineral drugs are achievable. Future research, therefore, should include heavy metal screening among siddha medicine users, especially among more vulnerable groups like children and pregnant women.

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^{5.} Three Cases of Lead Toxicity Associated with Consumption of Ayurvedic Medicines, A. Raviraja, Indian J Clin Biochem. 2010 Jul; 25(3): 326–329.

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^{8.} Ayurvedic herbal medicine and lead poisoning, Krishna S Gunturu,#1 Priyadharsini Nagarajan, J Hematol Oncol. 2011; 4: 51.



Analgesic, Antipyretic, and Anti-inflammatory properties of the SKM PYRO-H15 tablets

BACKGROUND:

SKM PYRO H-15 is the proprietary ayurvedic medicine indicated for viral infections associated with fever, pain, and inflammatory conditions. The recommended clinical dose of SKM PYRO H-15 for children is 1 tablet twice daily and for adults its 1 to 2 tablets twice daily. The composition of active ingredients per tablet is 472.5 mg. Besides, this study was taken to evaluate the analgesic, antipyretic, and anti-inflammatory efficacy of the SKM PYRO H-15 tablet preclinically to authenticate and augment clinical usage.

OBJECTIVES OF STUDY:

- ★ To determine the acute oral toxicity study of SKM PYRO H-15 proposed clinical dose as per OECD 423 test guidelines.
- ★ To determine the Peripheral and Central analgesic activity of SKM PYRO H-15 in the Mice model.
- ★ To determine the antipyretic effect of SKM PYRO H-15 on the Yeast-induced pyrexia model
- ★ To determine the anti-inflammatory effect of SKM PYRO H-15 on the Carrageenan-induced acute paw oedema mode



METHODOLOGY:

Dose Calculation

The dose for the experimental study was calculated by extrapolating the human dose to the animal dose based on the body surface area ratio. Accordingly, the human therapeutic dose of SKM PYRO H-15 is $945 \, \text{mg/day} - 1890 \, \text{mg/day}$ converted to rat dose as a low dose of $97.65 \, \text{mg/kg/day}$ and a high dose of $195.30 \, \text{mg/kg/day}$. The rat dose of SKM PYRO H-15 was fixed based on the human therapeutic dose.

Acute Oral toxicity study

Acute oral toxicity of SKM PYRO H-15 was evaluated by the acute toxic class method as per OECD test guideline 423. The acute oral toxicity study provides information about the dose range where the toxicity or lethality is expected and to classify the test substance according to Globally Harmonized System (GSH) for acute toxic class.

Animals used : Female Albino Wistar rats
Age and body weight : 8 to 12 weeks old; 180-220 g

Drug/Dose : SKM PYRO H-15 (2000mg/kg b. w. p. o.)

Duration of study : 14 days

The female non-pregnant rats were acclimatized and housed in the experimental condition one week before the experiment. Before experimentation, the animals were overnight fasted and provided water ad libitum.

The feed was withheld up to 4 hours after dosing. A single oral dose of 2000 mg/kg body weight of SKM PYRO H-15 was administered. After administration, each animal was individually observed for the first 30 minutes, followed by special attention for the first 4 h and periodically for 24 h, thereafter daily for 14 days. The evaluation parameters include changes in skin and fur, mucous membrane, eye, respiration, circulatory, central, and peripheral nervous system, and somatomotor activity and behavioral changes. The occurrence of salivation, diarrhea, lethargy, tremors, convulsions, sleep, and coma were monitored closely. If two out of three animals died, the dose was classified as hazardous. If one animal died, the test was repeated to ensure the toxic dose. If there were no toxic events or mortality, then the SKM PYRO H-15 tablet was categorized according to Globally Harmonized System (GSH) for acute toxic classification of chemicals.

Evaluation of Analgesic activity of SKM PYRO H-15

The analgesic effect of SKM PYRO H-15 against neuropathic pain (central analgesic) was evaluated by Eddy's hot plate method and against peripheral pain (Peripheral analgesic) was evaluated by acetic acid-induced abdominal writhing method.

Evaluation of central analgesic activity of SKM PYRO H-15 by Eddy's hot plate method

The central analgesic effect of SKM PYRO H-15 was evaluated by Eddy's hot plate method. The pre-screened Swiss albino mice that showed a reaction time of 3 to 5 sec were selected and randomly divided into four groups of six mice per each as follows.



Group	Treatment	No. of
		animals
Group-I	Normal control received saline solution at the dose of	6
	1 ml/kg, <i>p. o.</i>	
Group-II	Standard control received Pentazocine10 mg/kg i. p.	6
Group-III	Received SKM PYRO H-15 low dose 97.65 mg/kg p. o.	6
Group-IV	Received SKM PYRO H-15 high dose 195.3 mg/kg <i>p. o.</i>	6

Animals were placed on Eddy's hot plate maintained at a standard temperature of 55±1°C. The reaction time in control and treated animals was recorded till the animal showed licking or jumping movements. The cut-off time was considered as 10 sec.

The reaction time was recorded at 0, 30, 60, 90, and 120 min following administration of the test and standard drugs. These latency time values of the test were compared with the standard pentazocine and control normal saline treatments

Evaluation of the peripheral analgesic activity of SKM PYRO H-15 by Acetic acid-induced writhing method

The peripheral analgesic effect of SKM PYRO H-15 was evaluated by an acetic acid-induced writhing method. Twenty-four Swiss albino mice of both sexes were randomly divided into four groups of six mice per each as follows.

Group	Treatment	No. of
		animals
Group-I	Normal control received saline solution at the dose of	6
	1 ml/kg, <i>p. o.</i>	
Group-II	Standard control received diclofenac 20 mg/kg i. p.	6
Group-III	Received SKM PYRO H-15 low dose 97.65 mg/kg p. o.	6
Group-IV	Received SKM PYRO H-15 high dose 195.3 mg/kg p. o.	6

One hour after administration of diclofenac and SKM PYRO H-15, 0.6% glacial acetic acid (10 ml/kg) was given intraperitoneally (i. p.) to all the mice to induce pain characterized by abdominal constrictions or writhes that travel along the abdominal wall, sometimes accompanied by turning movements of the body and extension of the hind limbs.

The number of writhes observed in each mouse was counted for 15 minutes and recorded. The percentage protection against abdominal writhing was used to assess the degree of analgesia and was calculated by using the formula.

$$\% inhibition = \frac{Wc - Wt}{Wc} \times 100$$

% inhibition = $\frac{\text{Wc} - \text{Wt}}{\text{Wc}} \times 100$ Where Wc- Average number of writhing in control and Wt- Average number of writhing in test animals.

Evaluation of Antipyretic activity of SKM PYRO H-15

The antipyretic effect of SKM PYRO H-15 was evaluated by Brewer's yeast- induced pyrexia method. Rats were randomly divided into four groups six rats per each as follows

Group	Treatment	No. of animals
Group-I	Normal control received saline solution at the dose of	6
	1 ml/kg, <i>p. o.</i>	
Group-II	Standard control received paracetamol 100 mg/kg <i>p. o.</i>	6
Group-III	Received SKM PYRO H-15 low dose 97.65 mg/kg p. o.	6
Group-IV	Received SKM PYRO H-15 high dose 195.3 mg/kg <i>p. o.</i>	6

The normal body temperature of each selected rat was measured by using a digital thermometer. Pyrexia was induced by injection of 20% aqueous suspension of brewer's yeast 10 ml/kg in saline solution into the back side below the nape of the neck and injected site is massaged to spread. After that animal were fasted overnight with free access to water,

19 hrs after administration of yeast pyrexia was confirmed by an increase in temperature of more than 1°C, while animals showing less than 1°C rise in temperature were excluded from the experiment. Test substances and a control vehicle were administered and the rectal temperature of the animals was recorded at 1 hr intervals for 4 hr. The difference between the final and initial rectal temperature was registered for each time interval. The maximum reduction in rectal temperature in comparison to the control group was recorded.

Evaluation of Antipyretic activity of SKM PYRO H-15

The antipyretic effect of SKM PYRO H-15 was evaluated by Brewer's yeast-induced pyrexia method. Rats were randomly divided into four groups six rats per each as follows

Group	Treatment	No. of animals
Group-I	Normal control received saline solution at the dose of	6
	1 ml/kg, p. o.+ Carrageenan (1% w/v, 0.1 ml)	
Group-II	Standard control received diclofenac sodium 20 mg /kg	6
	P. O. + Carrageenan (1% w/v, 0.1 ml)	
Group-III	Received SKM PYRO H-15 low dose 97.65 mg/kg p. o.+	6
	Carrageenan (1% w/v, 0.1 ml)	
Group-IV	Received SKM PYRO H-15 high dose 195.3 mg/kg p. o.+	6
	Carrageenan (1% w/v, 0.1 ml)	

Acute inflammation was induced in all groups by injecting 0.1 ml of 1% w/v carrageenan into the sub-plantar region of the right hind paw of rats, 30 mins after administration of standard and test drugs. The paw volume was quantified using a digital plethysmometer before and at the 1st, 2nd, 3rd, and 4th hr after carrageenan administration.



The oedema volume of the paw and percent inhibition of oedema was calculated using the following formula:

$$EV = PVA-PVI$$

EV = edema volume, PVI = Paw volume before carrageenan administration (i.e. initial paw **EV = PVA-PVI** volume), and PVA = Paw volume after carrageenan administration.

$$\% inhibition = \frac{EVc - EVt}{EVc} \times 100$$
 EVc = Edema volume of control animals, EVt = Edema volume of test drug animals.

Results were presented as mean ± Standard error of the mean (SD) of sample replicates (n=6). Raw data were analyzed by using one way analyses of variance (ANOVA), followed by post hoc Dunnet's multiple comparison tests using SPSS V.17. P<0.05 was established to be statistically significant.

RESULTS AND DISCUSSION:

Effect of SKM PYRO H-15 on Observational and Behavioural Parameters in Acute Oral Toxicity Studies

Acute oral toxicity of the SKM PYRO H-15 was tested at the maximum dose of 2000 mg/kg. There were no toxic symptoms, mortality, observational changes, somatomotor changes, and behavioral changes observed after single oral dose administration, also there were no significant changes in the body weight, feed intake, and water intake during the 14 days observation period after acute oral dosing of SKM PYRO H-15. These results indicated that the SKM PYRO H-15 was found to be safer at the tested dose level of 2000 mg/kg. Therefore the lethal dose of 50% (LD50) of the polyherbal formulation was greater than 2000 mg/kg. According to the Globally Harmonized System (GHS) toxicity classification the SKM PYRO H-15 was classified as category 5 or unclassified.

Table 1: Effect of SKM PYRO H-15 on Observational and Behavioural **Parameters in Acute Oral Toxicity Studies**

					(Obsei	vatio	15	N		
S. No.	Parameters	0 hr	30 mins	1 hr	4 hr	24 hr	Day 1-3	Day 4-6		10-	Day 13- 14
1.	Fur & Skin	N	N	N	N	N	N	N	N	N	N
2.	Eyes(Exophthalmos, Lacrimation)	N	N	N	N	N	N	N	N	N	N
3.	Salivation	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB
4.	Respiration	N	N	N	N	N	N	N	N	N	N
5.	Urination	N	N	N	N	N	N	N	N	N	N
6.	Feces consistency	N	N	N	N	N	N	N	N	N	N
7.	Diarrhoea	AB	AB	AB	AB	AB	AB	AB	AB	AB	AE
8.	Sedation	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB
9.	Sleep	N	N	N	N	N	N	N	N	N	N
10.	Loss of righting reflex	AB	AB	AB	AB	AB	AB	AB	AB	AB	AE
11.	Writhing	AB	AB	AB	AB	AB	AB	AB	AB	AB	AE
12.	Itching	AB	AB	AB	AB	AB	AB	AB	AB	AB	AE
13.	Straub phenomena	AB	AB	AB	AB	AB	AB	AB	AB	AB	AE
14.	Piloerection	AB	AB	AB	AB	AB	AB	AB	AB	AB	AE
15.	Motor activity	N	N	N	N	N	N	N	N	N	N
16.	Grip strength	N	N	N	N	N	N	N	N	N	N
17.	Convulsion/Tremor/Coma	AB	AB	AB	AB	AB	AB	AB	AB	AB	ΑE
18.	Mortality	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Ni

AB- Absent, N- Normal

Effect of SKM PYRO H-15 on carrageenan-induced acute paw edema model

The anti-inflammatory property of the SKM PYRO H-15 was studied in the carrageenan-induced acute paw edema model. The standard diclofenac treatment showed a significant (P<0.001) anti-inflammatory effect after 3 hrs of carrageenan injection and the maximum inhibitory effect was observed after 4 hrs. The treatment of SKM PYRO H-15 produced dose-dependent anti-inflammatory action, the high-dose treatment showed moderate significant (P<0.01) antiinflammatory action after 3 hrs of carrageenan injection, and the more significant (P<0.001) inhibitory effect was observed after 4 hrs. The percentage of inhibition of inflammation was 34.96, 23.68, and 31.75 in diclofenac, SKM PYRO H-15 low dose and high dose treatmentrespectively. The antiinflammatory property of the SKM PYRO H-15 is almost nearer to the effect of standard diclofenac treatment (Table 5).

Table 5: The Anti-inflammatory activity of SKM PYRO H-15 on carrageenaninduced acute paw edema model

	Normal paw Paw volume in ml after carrageenan							
Treatment	volume (ml)		administration					
		1 hr	2 hr	3 hr	4 hr			
Group-I	1.86±0.18	6.07±0.56	6.78±0.47	6.99±0.76	7.18±0.32			
(Normal Control)	1.00±0.10	0.07±0.36	0.70±0.47	0.99±0.76	7.10±0.32	-		
Group-II								
(Diclofenac	2.04±0.15	6.38±1.21	6.47±0.82	5.31±0.34c	4.67±0.42°	34.96		
sodium 20 mg/kg)								
Group-III								
(SKM PYRO H15 -	2.02±0.38	6.27±0.37	6.98±0.54	6.28±0.27d	5.48±0.42 [∞]	23.68		
97.65 mg/kg)								
Group-IV								
(SKM PYRO H15-	1.95±0.31	6.49±0.33	6.91±0.32	5.49±0.60b	4.90±0.42c	31.75		
195.3 mg/kg)								

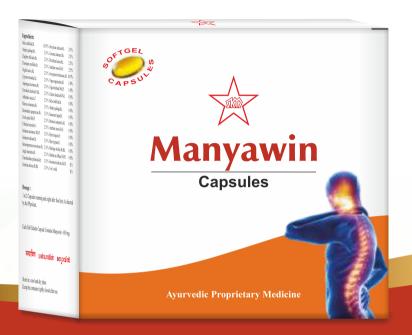
Values are expressed as mean ± SD, n=6. Symbols represent statistical significance a P<0.05; b P<0.01; c P<0.001 Vs Group I. d P<0.05; e P<0.01; f P<0.001 Vs Group II. Data were analyzed by one way ANOVA followed by post hoc Dunnett's multiple comparison tests.

KEY FINDINGS:

- ★The acute oral toxicity study results revealed that the treatment of SKM PYRO H-15 is safer up to the dose level of 2000 mg/kg.
- *According to the Globally Harmonized System (GHS) toxicity classification the SKM PYRO H-15 was classified as category 5 or unclassified.
- ★SKM PYRO H-15 showed dose-dependent central and peripheral analgesic action.
- ★ SKM PYRO H-15 showed dose-dependent anti-inflammatory action on the acute paw oedema model.
- ★The onset of anti-inflammatory action was moderate 3 hrs after administration of SKM PYRO H15 at the dose level of 195.3 mg/kg, but the standard of Diclofenac sodium (20 mg/kg) treatment showed more significant anti- inflammatory action after 3hrs of administration. The maximal anti- inflammatory action was observed 4 hrs after administration of SKM PYRO H-15, which shares the similar action of standard Diclofenac sodium.
- ★In conclusion, this study results authenticate the analgesic, antipyretic, and anti-inflammatory properties of the SKM PYRO-H15 tablets.

For Softgel Capsules

Cervical Spondylosis!





Active Herbal Ingredients

Bala

- Aids in rejuvenation and nourishment of the bone and joints
- · Helps to balance Vata dosha

Guduchi

- Reduces pain and inflammation in muscles and joints
- Aids in all type of arthritis

Sunthi

- Reduce swelling, redness, pain and stiffness
- Good for Cervical Spondylosis

Karpasa

- · Nourish the bones and joints
- Good in Neuro muscular disease

Punarnava

- Promotes comfortable movement of the joints
- Providing relief from joints experiencing pain

Dashamoola

- Pain-relieving and anti-inflammatory properties
- · Nourish the bone and joints

Eranda

- Boost the strength of the cartilage and bones
- Having pain-relieving & laxative properties

Rasna

- Good for Arthritis, Sciatica, Myalgia and spondylosis
- Managing arthritis and Spondylitis

Sigru

- Reduce swelling, redness, pain and stiffness
- Good for Cervical Spondylosis

Devadaru

- Reduce pain, swelling and difficulty in moving
- Relief from the symptoms of osteoarthritis

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