

Preclinical Study-To study toxicity profile of Polyherbal formulation.

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A study to test a drug, a procedure or another medical treatment in animals. The aim of a preclinical study is to collect data in support of the safety of the new treatment. Preclinical study is required before clinical trials in human on the started.

Before starting the study, a preclinical study was carried out with the following.

Aim and Objective of Study: to study the toxicity profile of plyherbal and objectives formulation in the management of diabetic neuropathy by using experimental animals like Wistar Rats.

Material: Capsule of polyherbal formulation and Wistar Rats.

Method:

It was a preclinical study which was carried out among rats. Wistar rats of either sex were used. Five rats were taken for experiment.

Weight range was 180-250gms. And were housed and feed under the CPCSEA guidelines.

The dose of the test drug was calculated as per body weight and dilution of per 2000mg/kg was made.

The animals were administered drugs orally and were observed for 14 days to find the acute toxicity profile. LD-50.

The study was approved by Institutional Animal Ethics committee Approval no. (IAEC/2013/11).

The study was carried out as per the guidelines of CPCSEA (Committee for the purpose of control and supervision of Experiments on Animals) and Institutional Animal Ethics Committee (IAEC) has been constituted to supervised and evaluate all aspects of the animal care and use program.

The animals were observed for 14 days to find the acute toxicity profile LD50

Plants : systematic Division

1] ashwagandha



[L. Name : Withania Somnifera]

Parts used : Roots

Ras : Tikta, Katu, Madhura

Guna : Laghu, Snigdha

Veerya : Ushna

Vipak : Madhura

Dose : 3 to 6 gms

Significance : Roots : Nervine disorders , Shothtara, Insomnia, Vedanasthapak, strengthen nerves
Nervine tonic, balya

[Database on Medicinal plants used in Ayurveda Vol . 2]

2] Manjishtha



[L. Name : Rubia Cordifolia]

Parts used : Roots

Ras: Madhura, Tikta, Kashaya

Guna : Guru

Veerya : Ushna

Vipak : Madhura

Significance : Roots : blood purifier, Tonic sheshmahara, Shothahara, Antidysentric, klednashak, Antiseptic

[Trease and Evans : Author : W. C. Evens]

[Bhavprakash nighantu page no. 90]

3)Guggulu



[L. Name

Ras : Tikta, Katu

Guna : Laghu, Ruksha

Veerya : Ushna

Vipak : Katu

Partts used : Niryasa

Significance : Nervine tonic, antispasmodic, painkiller, antiinflammatory, antihelmenthic, antiviral

[Bhavprakash nighantu page no. 70]

4] Kuchla



[L. Name : Nux Vomica]

Ras : Tikta, Katu

Guna : Ruksha, Laghu, Tikshna

Veerya : Ushna

Vipak : Katu

Parts used : Seeds

Significance : Antiinflammatory, stimulant to nerve, painkiller, antiseptic

Result :

Antimicrobial activity

Plant Parts Soxhlet extraction [Ether] Extract Bioassy

5] Shilajeet:



[L. Name: Euphorbia royleana and Trifolium repens]

Ras: Tikta, Lavan

Guna: Ruksha, Laghu, Tikshna

Veerya: Sheet; Vipak: Katu

Parts used: Decomposition of plant material

Description of Shilajeet:

Humidity: 12.54% Benzoic Acid: 6.42% Hippuric Acid: 5.53% Fatty Acid: 2.01%

Resin and Wax etc: 3.28 herbal content: 28.52%

Two type Shilajeet are available in market: Gomutra Gandhi Shilajeet has medical property. Karpur Gandhi Shilajeet not has such property.

Significance: Improving cognitive disorders and as a stimulant of cognitive activity in human, prevention of Alzheimer’s disease, include its action in genitourinary disorders, jaundice, digestive disorders, enlarged spleen, epilepsy, nervous disorders, chronic bronchitis and anaemia also useful for the treatment of kidney stones, edema and hemorrhoids as an internal antiseptic and to reduce anorexia

Animals used: Wistar rats of either sex in the management of diabetic neuropaths with special reference to Prameha Upadrava.

Results and conclusion: The pilyherbal formulation is safe for human being.

CPCSEA: Committee for the purpose of control and supervision on experiments on animals.

Observation :The five rats were be taken for the experimentation weight range between 180-250gms and were used and fed under the CPCSEA GUIDELINES.

The dose of test drugs were calculated as per the body weight and made the dilution as per 2000mg/kg.

The animals were administered polyherbal formulation by making solution/ dilution in the dose of 2000mg/kg orally.

And the animals were observed for 14days to determine the acute toxicity profile i.e. LD50. No mortality found.

Report (Blind Score)

Observation table:

Animal No. 1

	Parameter/Time	Normal Score	30/60min.	90min.
Awareness			1st	3rd
1	Alertness	4	4	4
2	Visual Placing	4	4	4
3	Sterotype	0	4	4
4	Passivity	0	0	0
Mood				

1	Grooming	4	4	4
2	Vocalization	0	0	0
3	Restlessness	0	0	0
4	Irritability	0	0	0
5	Fearfulness	0	0	0
Motor activity				
1	Spontaneous activity	4	4	4
2	Reactivity	4	4	4
3	Touch response	4	4	4
4	Pain response	4	4	4
Central stimulation				
1	Startle response	0	0	0
2	Straub response	0	0	0
3	Tremor	0	0	0
4	Convulsion	0	0	0
Posture				
1	Body Position	4	4	4
2	Limb Position	4	4	4

0 indicates that activity is absent in normal animals

4 indicated that activity is present in normal animals.

Motor co-ordination				
1	Staggering action	0	0	0
2	Abnormal gait	0	0	0
3	Writing reflux	0	0	0
Muscle tone				
1	Limb tone	4	4	4
2	Grip Strength	4	4	4
3	Body tone	4	4	4
4	Abdominal tone	0	0	0
Reflex				
1	Pinna	4	4	4
2	Cornea	4	4	4
3	Dpsilateral	4	4	4
Autonomic				
1	Writing	0	0	0
2	Pupils size	4	4	4
3	Exophthalmic	4	4	4
4	Urination	0	0	0

0 indicated that activity is absent in normal animals.

4 indicated that activity is present in normal animals.

Dose-2000mg/kg

Blind Screening of Ayurvedic formulation

Observation table-Animal no.2

Sr. no.	Parameter	Normal score	60min.
Awareness			
1	Alertness	4	4
2	Visual placing	4	4
3	Sterotype	0	0
4	Passivity	0	0
Mood			
1	Grooming	4	4
2	Vocalization	0	0
3	Restlessness	0	0
4	Irritability	0	0
5	Fearfulness	0	0
Motor activity			
1	Spontaneous activity	4	4
2	Reactivity	4	4
3	Touch response	4	4
4	Pain response	4	4
Central Stimulation			
1	Startle response	0	0
2	Straub response	0	0
3	Tremer	0	0
4	Convulsion	0	0
Posture			
1	Body position	4	4
2	Limb position	4	4

0 indicates that activity is absent in normal animals

4 indicated that activity is present in normal animals.

Motor co-ordination			
1	Staggering action	0	0
2	Abnormal gait	0	0
3	Writhing reflex	0	0
4	Somergault test	0	0
Muscle tone			
1	Limb tone	4	4
2	Grip strength	4	4
3	Body tone	4	4

4	Abdominal tone	0	0
Reflex			
1	Pinna	4	4
2	Cornea	4	4
3	Dpsilateral	4	4
Autonomic			
1	Writing	0	0
2	Pupils size	4	4
3	Exophthalmic	4	4
4	Urination	0	0

0 indicates that activity is absent in normal animals

4 indicated that activity is present in normal animals.

Another 3 Wistar rats of either sex were found similar identical observation in each animal. No mortality found. Polyherbal drugs does not contain any toxic material.

Result and Conclusion: The Polyherbal formulation is safe for human being.

CPCSEA- Committee for the purpose of control and supervision on experiments on animals.