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# **DRUG PROVING**

# Ficus Religiosa

A multicentric double blind Homoeopathic Pathogenetic Trial (drug proving) carried out by CCRH\*

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## **Abstract**

Objective: Objective of the study was to elicit the pharmacodynamic response of the drug, Ficus religiosa on healthy human beings in non-toxic doses.

Methodology: Drug was proved through a double-blind method and was a multi-centric study. Trial drug was proved in two potencies (30C and 200C) on 24 volunteers who were selected and declared apparently healthy during their pre-trial medical examination by specialists. The volunteers took 56 doses of each of the two potencies in three stages including one control stage for a varying period. The symptoms generated during the trial period were noted by the volunteers and elaborated and cross examined by the Proving Masters. The data obtained from different centers were compiled at proving-cum-data processing cell at CCRH headquarters after decoding the drug.

Observation: Out of the 17 volunteers who were on actual drug trial, 11 manifested symptoms. Drug was able to produce symptoms in each potency more or less on every part of the body. Some of the symptoms have been reproved which are mentioned in the fragmentary provings published in different literatures.

Conclusion: Symptoms appeared (new and reproved) during the proving trial will add to the literature available on the drug and benefit the research scholars and clinicians. This also needs verification through clinical application in different clinical conditions.

**Keywords:** homoeopathy; pharmacodynamic effect; homoeopathic pathogenetic trial; drug proving; ficus religiosa.

### Introduction

Ghose conducted proving of Ficus religiosa in 1899 after the incident of his brother-in-law having an attack of haematemesis in the year 1887. The attack was very alarming that his condition was declared to be totally hopeless. The late Dr. Mahendra Lal Sircar began to treat him from the very commencement of his illness; but unfortunately no medicine prescribed by him could arrest the disease. One day a *sannyasi* came to see him and suggested to procure a few fresh leaves of Ashwattha tree. The extracted juice of leaves was given

to his brother-in-law after each spell of vomiting of blood. The effect of the juice was instantaneous and marvellous to stop the haemorrhage. This recipe completely cured him. This inspired Dr. Ghose to prove this drug. He proved this drug on himself, his wife and also on a dog in the mother tincture form. He introduced Ficus religiosa to Homoeopathy in 1903. The proving made by him was not based on a drug proving protocol. So a systemic proving in potencies was necessary to get its pathogenetic power 1,2.

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# Objective

To elicit the pharmacodynamic response of the drug, Ficus religiosa on healthy human volunteers in non-toxic doses.

### Literature review

Botanical name : Ficus religiosa. Family : Moraceae

#### Common names<sup>3</sup>:

English : Sacred fig; Peepal tree Hindi : Pippal, pipli, pipar

Bengali : Ashathwa, Asud, Aswat, Aswattha

Gujrati : Jari, Pipro, Pipul Kannada : Aswaththa, Arali

Malayalam: Arayal, Arachu, Ashvatham

Marathi : Ashvatha, Pimpala

Punjabi : Pipal, Bhor

Tamil : Arasu, Ashwattha, Aswartham Telugu : Ravi, Ashvatthamu, Bodhi, Rai,

Raiga, Ragi

Assam : Ahant Oriya : Aswatha

# **Description**

A large glabrous tree usually at first epiphytic; bark grey, exfoliating in roundish, irregular flakes; leaves coriaceous, shining, long petioled, drooping, 10-18 cm long, ovate- round, entire, narrowed upwards and with the apex produced into a linear lanceolate tail 1/3<sup>rd</sup> of the whole length of the blade; base broad, rounded or truncate, or sometimes in young leaves, cordate; petioles 7-10 cm long, slender, terete, stipule minute, ovate, acute. Receptacles in pairs, auxillary, sessile,



smooth, depressed, globose, 1.25 cm in diameter, dark purple when ripe; basal bracts 3; spreading, coriaceous. Male flower few, only near the mouth of some receptacles, absent in others; sessile sepals 3, broadly ovate, stamen 1, filament short. Gall and fertile flowers sessile or pedicelled, the gall flowers predominating, many without a perianth; sepals 5, lanceolate, style short, stigma rounded<sup>4</sup>.

#### Distribution

Throughout India

## Part used in Homoeopathy

Tender leaves.

# Ayurvedic uses

Ficus religiosa is used in Ayurveda for gonorrhoea, diarrhoea, dysentery, haemorrhoids and gastric ulcer. The paste of powdered bark is useful for inflammatory swellings and in burns. Leaves are purgative and prescribed in wounds and skin diseases. Fruits are laxative and digestive. Dried fruits with water are useful in asthma. Seeds are laxative. The latex is useful in inflammation and haemorrhages<sup>3</sup>.

# **Materials and Methodology**

# Location and duration of study

The drug was proved at the Drug Proving Research Units (H) located at Kolkata (W.B.), Ghaziabad (U.P.) and Midnapore (W.B.) during 2003-04.

## **Participants**

Twenty four (24) apparently healthy volunteers, between the age group of 18-50 years, comprising of nineteen (19) males and five (5) females were enrolled for this study. Pre and Terminal Medical Examination (PME & TME) of the volunteers were carried out by General Physicians, Psychiatrists, Cardiologists, Ophthalmologists, ENT Specialists, Dermatologists, Gynaeco-logists and Radiologists at all the three centers to ascertain their health status.

### Drug

Ficus religiosa in 30C and 200C potencies was procured from M/s. Dr. Willmar Schwabe India Pvt. Ltd., India, in 100 ml. sealed phial of each dilution. Globules (number 30) were medicated with these attenuations at CCRH headquarters and sent to the Drug Proving Units in coded phials (both verum and placebo).

### Placebo

Placebo was made up of plain globules (size 30) moistened with plain alcohol (unsuccussed).

# Design

The study was conducted through 'placebo controlled double blind technique'.

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#### Method

Before commencing the study, all volunteers were screened as per the drug proving protocol of CCRH. Ethical approval was obtained and 'written informed consent' from each volunteer was obtained before starting the proving. Pre-trial Medical Examination (PME) was conducted to confirm health status of the volunteers. Volunteers declared healthy were enrolled in the study. Out of 24 volunteers, 17 were kept on drug (verum) and 07 were on placebo (control). All the volunteers were assigned code numbers and the coded drugs (including placebo) of different potencies were supplied to the centres in separate glass phials bearing code numbers of the respective volunteer.

The study consisted of three stages including the first control stage and other two stages of two different potencies viz. 30C and 200C. Each potency of the drug was given in 56 doses and the duration of each stage was 14 days (4 doses daily for 14 days, i.e. 56 doses).

The volunteers were asked to take 4-6 globules of a particular potency of the coded drug, four times a day, dry on tongue.

The volunteers were instructed to note down the details of their feelings or changes in mind and body in 'Prover's Day Book Proforma' daily, after taking the drug.

If sign(s) / symptoms(s) appeared:

The volunteers were asked to stop taking the drug as soon as they felt any change or any sign(s) and/or symptoms(s) developed during the trial.

The volunteers noted down the new sign(s) and/ or symptoms(s), their progress and the number of doses after which each sign/symptom appeared. The date, time of onset and duration upto which the symptoms persisted were also noted. Intake of drug remained suspended till the sign(s) and/or symptoms(s) totally disappeared.

If no sign(s) / symptoms (s) appeared:

In case of non-appearance of any symptom, the volunteers were instructed to note down 'No symptom' with date and time of intake of the respective dose of drug.

After the disappearance of sign(s) and/or symptom(s) developed by the drug, the volunteers waited for a further period of 07 days before restarting the remaining doses of that stage. The volunteers took the remaining doses of the drug again in the same

dose schedule as stated above. In case of further appearance of new sign(s) and / or symptom(s) or reappearance of the earlier sign(s) and /or symptom(s), the same procedure as stated above was followed till a volunteer completed 56 doses of that potency.

Before the administration of subsequent potencies (at subsequent stages) of the drug, the volunteers were kept on a rest period for 14 days and asked to take the next potency in the same procedure as mentioned above, till the completion of 56 doses.

Each volunteer was daily interrogated by the Proving Master to verify the sign(s) and/or symptom(s) recorded by the volunteer. The complete symptoms verified by the Proving Masters were recorded in 'Prover's Day Book Proforma' alongwith the details related to the location, sensation, modalities and concomitants of the symptoms, if any, in 'Symptoms Elaboration Proforma'.

During the course of proving each volunteer was advised for specific laboratory investigation(s) to rule out any cause for appearance of symptom(s). Laboratory tests were performed to facilitate observation of any correlation between the subjective and objective changes during the course of proving. The expert opinion of the honorary consultant(s) was taken, whenever needed.

After completion of the trial of all potencies, the volunteers were examined by the specialists again, called 'Terminal Medical Examination' (TME).

On completion of all the respective stages of the proving, the compilation of data recorded in 'Prover's Day Book Proforma', 'Symptoms Elaboration Proforma', 'Pathological Report Sheets' and 'Terminal Medical Examination Sheets', was done at the headquarter by the Drug Proving-cum-Data Processing Cell. After decoding the proved drug, sign(s) and/or symptom(s) generated by the volunteers kept on the drug were separated from those generated by the volunteers kept on placebo. The sign(s) and/or symptom(s) which appeared in placebo as well as drug groups were not taken into consideration while compiling the symptomatology of the drug.

# Results

In Drug Proving Research Unit (DPRU), Kolkata 05 out of 07 volunteers, manifested symptoms. In DPRU, Midnapore 06 out of 10 volunteers reported symptoms, while in DPRU, Ghaziabad out of 07 volunteers, none reported any symptom following the administration of drug.

# Symptoms observed during proving of the drug

- In parenthesis, 1<sup>st</sup> number after every symptom denotes number of volunteers produced that particular symptom and 2<sup>nd</sup> number denotes potency used.
- agg. (Aggravation), amel. (Amelioration).
- Symptoms produced during the pathogenetic trial of the drug were compared with the homoeopathic literature cited in the reference and those symptoms which were found in the literature, shown in **bold**, superscripted with a numerical that refers to the respective literature.

## Symptoms Observed

## Mind

Easily angered from trifles or contradiction (1, 30C)

## Vertigo

- Vertigo<sup>5</sup>, agg. in morning, on opening eyes (1, 200C)
- Vertigo, agg. in morning, on rising from bed, , amel. after taking rest (1,200C)
- Vertigo, agg. after standing for a long time (1, 30C)

### Head

- Headache<sup>5,6,7</sup>, heaviness with coryza and pain in throat (2, 30C)
- Headache with malaise and pain in left hip and left foot (1, 30C)
- Aching in head with bursting sensation in eye balls, agg. by walking, cold water application, amel. pressure, hot application (1, 200C)
- Severe pain in right side of head with heaviness and difficulty in concentration during study, agg. light, amel. washing with cold water (1, 30C)
- Bursting headache in frontal region, agg. eating, masturbation, night, amel. sleep, tight bandage (1,30C)
- Throbbing pain in frontal region, agg. while studying, amel. open fresh air, sleep (1,30C)
- Throbbing pain in frontal region with nausea, agg. eating, amel. by hard pressure (1, 30C)
- Pain in occipital region goes to temporal region, agg. by stooping, amel. by hot application (1,30C)
- Aching in occipital region, agg. morning (1,200C)

#### Eye

- Bursting pain in eyeballs, agg. walking (1, 200C)
- Stye on lower eyelid with throbbing pain and

redness of eyeball, amel. warm application (1, 200C)

### Nose

- Coryza; sneezing with heaviness in whole head (1,30C)
- Coryza with severe sneezing (1, 30C)
- Sneezing with running nose, watery discharge, agg. in evening (1, 30C)

#### Mouth

- Salivation from mouth, agg. after meal, spicy food (1, 30C)
- Ulcers on tongue; tongue swollen, painful, agg. taking warm things (1, 30C)
- Rawness in throat with great thirst (1, 30C)
- Ulceration inside the mouth, right side of upper jaw,redness, rawness with swelling. Burning sensation, agg. touch, swallowing, drinking cold water, spicyfood. Sensation as if whole mouth is burnt (1, 200C)

### Throat

Pain in throat with dryness and rawness (3, 30C)

#### Abdomen

- Whole abdomen distended with accumulation of gas, agg. after spicy food (1, 30C)
- Pain in abdomen after taking food, followed by loose stools (1, 200C)
- Pain in lower abdomen <sup>6,7</sup> with nausea, agg. in morning (1, 30C)

#### Rectum

- Constipation with headache (1, 200C)
- Constipation with vertigo (1, 200C)
- Burning sensation in anus after passing stool, amel. cold application (1, 200C)

# Stool

- Stool large, dry (1, 200C)
- Loose watery stool, agg. morning, waking up, after taking milk products (1,30C)
- Loose stools, 6-7 times/day, agg. morning. Stool mixed with mucus and pain in abdomen, agg. after taking food (1, 200C)

### Male

Desire to masturbate (1, 30C)

### Cough

**Dry cough** 1,5,7 of long duration, agg. in morning,

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evening, while speaking, amel. drinking cold water (1, 30C)

- Cough with thin expectoration (1, 30C)
- Cough with white loose expectoration (1, 30C)

#### Extremities

- Pain in joints of lower extremities, sensation as if broken down, agg. morning, amel. lying down (1, 30C)
- Pain in left hip extending to whole foot, agg. evening (1,30C)
- Stitching pain in thighs, calves, amel. pressure (1, 30C)

### Sleep

Sleepiness, drowsiness with pain in lower extremities (1, 30C)

#### Fever

- High fever with coryza, agg. morning (1, 30C)
- Feverish feeling with heaviness of head and vertigo (1, 30C)

#### Generalities

- Bodyache, agg. morning, cold air, amel. warm drinks, warm application (1, 30C)
- Great dullness, drowsiness with pain in long bones (1, 30C)
- General weakness (1, 30C)
- Malaise with pain in left hip and foot (1, 30C)

#### **Discussion**

This drug was initially proved in mother tincture by Ghose. The Council initiated its proving in different potencies at three centers. A total number of 24 volunteers participated in drug proving program. 17 volunteers were kept on actual drug and 07 on placebo. Out of 17 volunteers, 11 manifested symptoms. At DPRU, Ghaziabad, none of the volunteers manifested symptoms. Drug was able to produce mostly physical symptoms more or less on every part of the body. Only two symptoms i.e. *headache* and *pain in throat* with dryness and rawness were appeared in more than one volunteer. Four symptoms were reproved which are already available in the literature of fragmentary proving. These were *vertigo*, *headache*, *pain in lower abdomen* and *dry cough*.

This drug seems to be of value in conditions like vertigo, headache, coryza, aphthous ulcers, cough and fever. It has also shown affinity for the digestive system for distension of whole abdomen with gas, pain in

abdomen after taking food, pain in lower abdomen with nausea, constipation and diarrhoea. These symptoms may help in clinical application of the drug.

# Conclusion

Symptoms appeared (new and re-proved) during the trial will add to the available literature on this medicine and benefit the research scholars and clinicians. However, these proven symptoms need further verification through clinical application in different settings.

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