

SUMMARY of SENSORIL® CLINICAL TRIALS

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SEVEN (7) PUBLISHED STUDIES

1 2008 Clinical Trial – Stress Study

(Auddy B, et al. 2008. A standardized *Withania somnifera* extract significantly reduces stress-related parameters in chronically stressed humans; A double-blind, randomized, placebo-controlled study. JANA 11:50-56)

| Design | # of Subjects | Duration | Dose |
|---|--|----------|--|
| Randomized, double-blind, placebo-controlled parallel study | 98 healthy subjects with mild to moderate stress | 60 days | 125 mg once daily 125 mg twice daily 250 mg twice daily Placebo |

Methods: Researchers evaluated a series of objective and subjective variables

Results:

- Significant reduction in cortisol and C-reactive protein, and significant increase in DHEA at all doses
- Significant reduction in fasting blood sugar, cholesterol, and triglycerides at the 125 mg twice daily dose and 250 mg twice daily dose
- Significant reduction in stress, anxiety, irritability, inability to concentrate, forgetfulness, sleeplessness, fatigue, and other subjective indicators of stress at all doses

2 2013 Bipolar Study – Cognitive Dysfunction in Bipolar Disorder

(Chengappa KNR, et al. 2013. Randomized placebo-controlled adjunctive study of an extract of *Withania somnifera* for cognitive dysfunction in bipolar disorder. J Clin Psych 74(11):1076-1083)

| Design | # of Subjects | Duration | Dose |
|---|---|----------|-------------------------------|
| Randomized, double-blind, placebo-controlled parallel study | 53 subjects with diagnosed bipolar disorder who were symptom-free during the study period | 8 weeks | 250 mg twice daily Placebo |

Methods: Researchers conducted a series of validated cognitive function tests

Results:

- Cognitive testing evaluated executive functioning, processing and psychomotor speed, attention, and memory based on Set Shifting, Strategic Target Detection, Auditory Digit Span, Word List Memory, Finger Tapping, and Flanker tests
- Consumption of Sensoril® resulted in significantly greater working memory, reaction time, and cognitive capacity

3 2013 Pain Study – Hot Air Pain Model

(Nalini P, et al. 2013. Evaluation of the analgesic activity of standardized aqueous extract of *Withania somnifera* in healthy human volunteers using Hot Air Pain Model. Res J Life Sci 1(2):1-6)

| Design | # of Subjects | Duration | Dose |
|--|---------------------|---|----------------------------|
| Randomized, double-blind, placebo-controlled crossover study | 12 healthy subjects | 1 day followed by a 14 day washout period followed by 1 day crossover | 1000 mg taken once placebo |

Methods: Researchers used a hot air model to measure resistance to pain

Results:

- Significant increase in resistance to pain 3 hours after consumption of Sensoril®
- This study provides further evidence that Sensoril® is fast acting and experiential

4 2013 Cognitive & Psychomotor Performance Study

(Pingali U, et al. 2013. Effect of standardized aqueous extract of *Withania somnifera* on tests of cognitive and psychomotor performance in healthy human participants. Pharmacogn Res 6(1):12-18)

| Design | # of Subjects | Duration | Dose |
|--|---------------------|--|----------------------------------|
| Randomized, double-blind, placebo-controlled crossover study | 20 healthy subjects | 14 days followed by 14 day washout period followed by 14 day crossover | 500 mg taken twice daily placebo |

Methods: Researchers conducted a series of validated cognitive function tests

Results:

- Significant improvements in the following tests:
 - Reaction Time (measures attention and sensory motor performance)
 - Digital System Substitution (measures attention, response speed, integration, and visual-motor coordination)
 - Digit Vigilance Task (measures alertness, vigilance, and selective capacity)
 - Card Sorting (measures sensory, motor, integrative, and executive functions)
- This study demonstrated that daily consumption of Sensoril® led to greater working memory, reaction time, and ability to process and store information

5 2013 Mental Stress & Cardiovascular Effects Study

(Pingali U, et al. 2013. Effect of *Withania somnifera* extract on mental stress induced changes in hemodynamic properties and arterial wave reflections in healthy subjects. Curr Top Nutraceutical Res 11(4):151-158)

| Design | # of Subjects | Duration | Dose |
|--|---------------------|--|----------------------------------|
| Randomized, double-blind, placebo-controlled crossover study | 20 healthy subjects | 14 days followed by 14 day washout period followed by 14 day crossover | 500 mg taken twice daily placebo |

Methods: Stress was induced through a mental stress test with cardiovascular effects measured

Results:

- Significant improvement in augmentation index (pulse pressure, arterial stiffness, and wave reflections)
- Significant reduction in blood pressure, serum cortisol, C-reactive protein, and MDA (measure of lipid peroxidation)

6 2014 Endothelial Dysfunction Study I

(Pingali U, et al. 2014. Evaluation of a highly standardized *Withania somnifera* extract on endothelial dysfunction and biomarkers of oxidative stress in patients with type 2 diabetes mellitus: A randomized, double blind, placebo controlled study. Int J Ayurveda Pharma Res 2(3):22-32)

| Design | # of Subjects | Duration | Dose |
|---|----------------------------------|----------|---|
| Randomized, double-blind, placebo-controlled parallel study | 60 subjects with Type 2 diabetes | 12 weeks | 250 mg twice daily 500 mg twice daily Placebo |

Methods: Researchers evaluated cardiovascular health benefits of each treatment based on endothelial function and other parameters, as well as biomarkers of oxidative stress.

Results:

- Consumption of both treatments led to significant improvements in endothelial function based on Reflective Index, as well as C-reactive protein, blood lipids, and biomarkers of oxidative stress which demonstrates Sensoril's advanced cardiovascular health benefits.

7 2014 Endothelial Function Study II (Includes a Combination with Capros®)

(Pingali U, et al. 2014. A comparative study to evaluate the effect of highly standardised aqueous extracts of *Phyllanthus emblica*, *Withania somnifera* and their combination on endothelial dysfunction and biomarkers in patients with type II diabetes mellitus. Int J Pharm Sci Res 5(7):2687-2697)

| Design | # of Subjects | Duration | Dose |
|--|----------------------------------|----------|---|
| Randomized, double-blind, parallel study | 30 subjects with Type 2 diabetes | 12 weeks | 500 mg Sensoril® twice daily or 250 mg Sensoril® + 250 mg Capros® twice daily |

Methods: Researchers evaluated cardiovascular health benefits of each treatment based on endothelial function and other parameters, as well as biomarkers of oxidative stress.

Results:

- Consumption of both treatments led to significant improvements in endothelial function based on Reflective Index, as well as C-reactive protein, blood lipids, and biomarkers of oxidative stress which demonstrates Sensoril's advanced cardiovascular health benefits.

THREE (3) UNPUBLISHED STUDIES – (Confidential details available under NDA)

1 2014 Pain Study – Mechanical Pain Model

(Nalini P, et al. Evaluation of analgesic activity of standardized aqueous extract of *Withania somnifera* in healthy human volunteers using mechanical pain model. Submitted for publication)

2 2014 Cardiovascular Changes in Healthy Humans

(Rani PU, et al. Evaluation of effect of *Withania somnifera* (Sensoril®) on cold pressor test induced cardiovascular changes in healthy human subjects. Submitted for publication)

3 2015 Joint Health Study

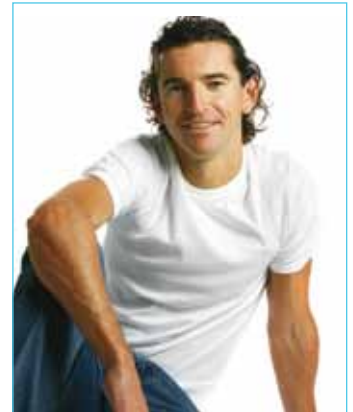
(Rani PU, et al. A randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and tolerability of *Withania somnifera* 250 mg and *Withania somnifera* 125 mg in patients with osteoarthritis knee. Submitted for publication)

Based on extensive testing including 10 human clinical trials, Sensoril[®] features the following structure/function claims which are in accordance with the requirements of the Dietary Supplement Health and Education Act of 1994.



STRESS

- Helps the body cope with stress *
- Promotes a calming, relaxing state of mind *
- Helps increase resistance to stress, tension, and irritability *
- Helps to reduce physical, emotional, and mental stress and fatigue *
- Helps promote a positive mind and mood *
- Helps to alleviate the effects of stress and tension *
- Enhances feelings of emotional well-being *



ENERGY

- Enhances energy levels while helping to alleviate fatigue *
- Boosts energy and reduces fatigue *
- Helps restore and sustain energy levels *
- Boosts energy levels *



MENTAL COGNITION

- Helps enhance focus and mental stamina *
- Helps promote mental clarity and concentration *

HEALTHY JOINT FUNCTION †

- Promotes healthy joint function *
- Supports healthy joint function *
- Maintains healthy joint function *

CARDIOVASCULAR HEALTH †

- Supports healthy cardiovascular function *
- Helps support cholesterol levels that are already within the normal range *

GLUCOSE RELEASE †

- Helps support blood sugar levels that are already within the normal range *

SLEEP

- Helps promote more restful sleep *
- Reduces stress to help promote more restful sleep *
- Helps promote better sleep *
- Reduces stress to help promote better sleep *



† 125 mg twice daily dose.

Sensoril[®] is a registered trademark of Natreon, Inc. and the product is protected under U.S. Patents 6,153,198 and 7,318,938.

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