

Scientific Studies

FROM THE ASHWAGANDHA EXPERTS. THAT'S ALL WE DO.



THE MOST CLINICALLY STUDIED ASHWAGANDHA ROOT EXTRACT IN THE WORLD

- Industry leader in clinical trials and research investigating the effectiveness of Ashwagandha.
- Largest pool of research studies with 50 studies: 30 published studies, 6 additional studies completed and in peer review, and 14 ongoing studies.
- Following the gold standard: Double-blind, Placebo-controlled, Randomized studies.
- Our trials are on healthy populations to mirror our mainstream customer base.
- Our publications are of academia standard, all in PubMed-indexed medicine journals.
- The principal investigators are leading researchers with established publication records.

STRESS RELIEF AND WELLNESS

STRESS AND ANXIETY



300mg/ Twice daily

Participants

- A 44% reduction in Perceived Stress Scale scores (p<0.001).
- A 27.9% reduction in Serum Cortisol levels (p<0.05).
- A 72.3% reduction in total General Health Questionnaire 28 scores (p<0.001).

 The GHQ-28 domain scores for Somatic, Anxiety and Insomnia, Social Dysfunction, and Severe Depression reduced significantly by 76.1%, 69.7%, 68.1%, and 79.3% respectively (p<0.001).
 - A 71.6% reduction in total <u>Depression Anxiety Stress Scale</u> score (p<0.001). The DASS scores for Depression, Anxiety, and Stress domains reduced significantly by 77.0%, 75.6%, and 64.2% respectively (p<0.001).

Chandrasekhar, K., Kapoor, J., & Anishetty, S. (2012) A prospective, randomized double-blind, placebo-controlled study of safety and efficacy of a high-concentration full-spectrum extract of ashwagandha root in reducing stress and anxiety in adults. *Indian journal of psychological medicine*, 34(3), 255–262.

STRESS AND STRESS-RELATED FOOD CRAVINGS



300mg/ Twice daily

Participants

- A 32.7% reduction in Perceived Stress Scale scores (p<0.05).
- Food Cravings Questionnaire scores for Planning, Positive and Negative Reinforcement, Lack of Control, Emotion, and Environment domains reduced significantly (p<0.05).
- A 22.2% decrease was observed in Serum Cortisol levels (p<0.05).
- A 3% and 2.9% reduction in Body Weight and Body Mass Index respectively (p<0.05).
- A 19.2% increase in Oxford Happiness Questionnaire scores (p<0.05).
- A 20.4% and 15.8% reduction in Three Factor Eating Questionnaire scores for "Uncontrolled" and "Emotional Eating Behavior" were observed (p<0.05).

Choudhary, D., Bhattacharyya, S., & Joshi, K. (2017). Body Weight Management in Adults Under Chronic Stress Through Treatment with Ashwagandha Root Extract: A Double-Blind, Randomized, Placebo-Controlled Trial. *Journal of evidence-based complementary & alternative medicine*, 22(1), 96-106.

STRESS, SLEEP, AND ANXIETY



125/300mg Twice daily

8 Weeks

58 Participants

- A 33.7% and 38.3% reduction in Perceived Stress Scale scores for 250mg/day and 600mg/day respectively (p<0.001).
- A 16.4% and 32.6% reduction in Serum Cortisol levels for 250mg/day and 600mg/day respectively.
- A 13.0% and 16.3% decrease in Hamilton Anxiety Scale scores for 250mg/day and 600mg/day (p<0.05) respectively.
- A 35.2% and 46.0% decrease in Sleep Quality scores for 250mg/day and 600mg/day respectively, resulting in greater quality of sleep.

Salve, J., Pate, S., Debnath, K., & Langade, D. (2019). Adaptogenic and Anxiolytic Effects of Ashwagandha Root Extract in Healthy Adults: A Double-blind, Randomized, Placebo-controlled Clinical Study. *Cureus*, 11(12), e6466.

SLEEP AND ANXIETY



300mg/ Twice daily

Participants

• Sleep Actigraphy Parameters:

- A 30.3% decrease in Sleep Onset Latency (p<0.002).
- A 22.5% decrease in Wake After Sleep Onset.
- A 19.0% increase in Total Sleep Time.
- A 10.3% increase in Sleep Efficiency (p<0.001).
- A 7.9% increase in Total Time in Bed.
- A 30.0% decrease in the Pittsburgh Sleep Quality Index, indicating better sleep (p<0.0001)
- A 21.6% decrease in the Hamilton Anxiety Scale scores.
- A significant increase in Mental Alertness on Rising scores from 10.3% at baseline to 69.2% at the end of the study.
- A significant increase in Sleep Quality (p<0.002).

Langade, D., Kanchi, S., Salve, J., Debnath, K., & Ambegaokar, D. (2019). Efficacy and Safety of Ashwagandha (*Withania somnifera*) Root Extract in Insomnia and Anxiety: A Double-blind, Randomized, Placebo-controlled Study. *Cureus*, 11(9), e5797.

SLEEP AND ANXIETY



300mg/ Twice daily

8 Weeks

80 Participants **Sleep Actigraphy Parameters:**

- A 15.5% and 33.5% decrease in Sleep Onset Latency in healthy and insomnia subjects respectively (p<0.0001).
- A 29.3% and 22.7% decrease in Wake After Sleep Onset in healthy and insomnia subjects respectively (p<0.0001).
- A 3.2% and 11.3% increase in Sleep Efficiency in healthy and insomnia subjects respectively (p<0.0001).
- A 22.2% and 26.2% decrease in the Pittsburgh Sleep Quality Index scores in both healthy and insomnia subjects respectively (p<0.0001), indicating better sleep.
- A 29.2% decrease in the Hamilton Anxiety Scale scores for Insomnia subjects (p<0.0001).
- A 17.9% and 36.0% decrease in Mental Alertness on Rising scores for healthy and insomnia subjects respectively (p<0.0001).
- A 31.6% and 45.3% increase in Sleep Quality in both healthy and insomnia subjects respectively.

Langade, D., Thakare, V., Kanchi, S., & Kelgane, S. (2020). Clinical evaluation of the pharmacological impact of ashwagandha root extract on sleep in healthy volunteers and insomnia patients: A double-blind, randomized, parallel-group, placebo-controlled study. *Journal of Ethnopharmacology*: 264:113276.

ELDERLY HEALTH

SLEEP AND GENERAL WELL-BEING IN ELDERLY



300mg/ Twice daily

- A 24.2%, 22.4%, 18.9%, 5.6%, and 9.8% increase in WHO-QOL scores for the Global, Physical, Psychological, Social Relationship, and Environmental domains respectively (p<0.0001).
- A 53.1% reduction in Mental Alertness on Rising scores indicates increased alertness (p<0.05).

12 Weeks

Participants

- A 57.1% reduction in Sleep Quality scores indicating an increase in the quality of sleep (p<0.0001).
- A 33.5% reduction in the Sleepiness Scale scores, indicates improved and better quality of sleep.

Kelgane, S. B., Salve, J., Sampara, P., & Debnath, K. (2020). Efficacy and Tolerability of Ashwagandha Root Extract in the Elderly for Improvement of General Well-being and Sleep: A Prospective, Randomized, Double-blind, Placebo-controlled Study. *Cureus*, 12(2), e7083.

FRAILTY IN OLDER ADULTS



300mg/ Twice daily

- A 12.6% reduction in Frailty Assessment and Screening Tool scores indicates increased alertness (p<0.05).
- A 19.3% improvement in the 6 Minute Walking Test scores.
- A 40.15 % reduction in the Pittsburgh Sleep Quality Index scores, indicates better sleep (p<0.001).
- A 17.98% improvement in Mini-Mental State Exam scores (p<0.001).
- A 8.06% increase in quality of life assessed by Short Form-12 Questionnaire (p<0.001) scores.

50 Participants

A Double-Blind, Randomized, Parallel, Single-Center, Two-arm, Placebo Controlled Clinical Study to Assess the Efficacy and Safety of KSM-66 Ashwagandha® Capsule (300 mg) in Management of Frailty in Older Adults.

CARDIORESPIRATORY ENDURANCE



300mg/ Twice daily

- A 11.3% and 13.6% increase at the end of 8 and 12 weeks in Maximal Oxygen Consumption (VO, max) respectively (p<0.001).
- A 14.8%, 19.7%, 21.6%, and 9.7% increase in WHO-QOL scores for the Physical Health, Psychological, Social Relationship, and Environmental domains respectively (p<0.05).

Choudhary, B., Shetty, A., & Langade, D. G. (2015). Efficacy of Ashwagandha (Withania somnifera [L.] Dunal) in improving cardiorespiratory endurance in healthy athletic adults. Ayu, 36(1), 63–68.

49 Participants

CARDIORESPIRATORY ENDURANCE AND RECOVERY



300mg/ Twice daily

- A 16.4% increase in Maximal Oxygen Consumption, VO, max (p=0.0074).
- A 37.36%, 60.71%, and 59.27% increases in the Recovery-Stress Questionnaire scores for the General Stress, Fatigue, and General Well-being domains respectively (p<0.0001).
 - A 6.67% increase in Total Quality Recovery scores (p<0.0001).
- A 45.2% decrease in Daily Analysis of Life Demands for Athletes scores (p<0.0001).
- A 10.59% increase in the Antioxidant levels.

50 Participants Tiwari, S., Gupta, S. K., & Pathak, A. K. (2021). A double-blind, randomized, placebo-controlled trial on the effect of Ashwagandha (*Withania somnifera Dunal.*) root extract in improving cardiorespiratory endurance and recovery in healthy athletic adults. *Journal of Ethnopharmacology*, 113929.

MUSCLE STRENGTH, RECOVERY AND TESTOSTERONE



300mg/ Twice daily

- A 15.3% increase in Serum Testosterone levels (p<0.05).
- A 138.7% and 52% increases in Muscle Strength for Bench Press and Leg Extension exercises respectively (p<0.05).
- A 8.1%, 17.1%, and 3.3% increases in Muscle Size for Thigh, Arm, and Chest respectively (p<0.05).
- A 3.5% reduction in Average Body Fat (p<0.05).
- A significant reduction in Serum Creatine Kinase levels indicates faster recovery.

50 Participants Wankhede, S., Langade, D., Joshi, K., Sinha, S. R., & Bhattacharyya, S. (2015). Examining the effect of *Withania somnifera* supplementation on muscle strength and recovery: a randomized controlled trial. *Journal of the International Society of Sports Nutrition*, 12, 43

MUSCLE STRENGTH AND ENDURANCE



00mg/ wice daily A 23.5% increase in Muscle Strength for bench press in males and a 22.8% increase in females, along with a 15% increase in leg extension exercises for males and a 9.9% increase for females.

8 Weeks

Participants

- An overall 5.2%, 3.5%, and 4.1% increase in Muscle Size for Arm (p<0.0001), Thigh, and Chest respectively.
- An overall 1.7% reduction in Average Body Fat.
- A 9.51% and 7.15 % increase in Maximal Oxygen Consumption (VO₂ max) in both males and females respectively (p<0.0001).

Verma N et al (2023). Effects of Ashwagandha (*Withania somnifera*) standardized root extract on physical endurance and VO2 max in healthy adults performing resistance training: An eight-week, prospective, randomized, double-blind, placebo-controlled study *F1000Research 2023*, 12:335.

MUSCLE RECOVERY AND TESTOSTERONE



300mg/ Twice daily

- An 8.11% and 10.07% increase in Free Testosterone and Total Testosterone levels in males (p<0.001 and p<0.0001).
- An overall 7.19% reduction in the Serum Creatinine Phosphokinase levels indicates faster recovery (p<0.0001).
- No significant increase was found in Testosterone levels in women.

Verma N et al (2023). Effect of Ashwagandha Root Extract on Serum Testosterone and Muscle Recovery in Strength Training. International Journal of Medical and Pharmaceutical Research. Volume: 4 Issue:5: Page No: 371-381.

80 Participants

MALE FERTILITY AND TESTOSTERONE



225mg/ Thrice daily

- A 167% increase in **Sperm Concentration** (p<0.001).
- A 53% increase in Semen Volume (p<0.001).
- A 57% increase in Sperm Motility (p<0.001).
- A 17% increase in Serum Testosterone levels (p<0.001).
- A 34% improvement in Serum Luteinizing Hormone (p<0.001).

Ambiye, V. R., Langade, D., Dongre, S., Aptikar, P., Kulkarni, M., & Dongre, A. (2013). Clinical Evaluation of the Spermatogenic Activity of the Root Extract of Ashwagandha (*Withania somnifera*) in Oligospermic Males: A Pilot Study. *Evidence-based complementary and alternative medicine:* eCAM, 2013, 571420.

12 Weeks

46 Participants

SEXUAL WELLNESS IN MEN



300mg/ Twice daily

Participants

50

- The Derogatis Interview for Sexual Functioning (DISF) domain scores for Sexual Fantasy/Functions, Arousal, Orgasm, and Sexual Drive improved significantly by 3.64%, 14.3%, 6.12%, and 11.35% respectively (p<0.0001).
- A 16.65% increase in Serum Testosterone levels (p<0.0001).
- A 3.94% decrease in Serum Prolactin levels.
 - The Short Form-36 Quality of Life Questionnaire domain scores for Physical Functioning, Energy/Fatigue, Emotional Well-being, Social Functioning, Pain, and General Health, improved significantly by 31.2%, 18.37%, 26.18%, 14.7%, 35.25%, and 11.07% respectively.

Chauhan, S., Srivastava, M. K., & Pathak, A. K. (2022). Effect of standardized root extract of ashwagandha (*Withania somnifera*) on well-being and sexual performance in adult males: A randomized controlled trial. *Health science reports*, 5(4), e741.

MALE FERTILITY, SEXUAL WELLNESS AND TESTOSTERONE IN MEN



300mg/ Twice daily

- A 14.3% increase in Serum Testosterone levels (p<0.05).
- A 10.43% increase in **Dihydrotestosterone** levels.
- A 26.4%, 32.14%, and 19.76% increase in Semen Volume, Sperm Count, and Sperm Vitality parameters respectively (p<0.05).

8 Weeks

- A 112.84% and 108.12% increase in the Level of Sexual Desire scores and Number of Satisfying Sexual Encounters respectively.
- 93 Participants
- The International Index of Erectile Function domain scores for Erectile Function, Orgasmic Function, Sexual Desire, and Intercourse Satisfaction improved significantly by 12.11%, 19.03%, 31.53%, and 29% respectively. The total IIEF score improved by 18.23%.
- A 15.52% increase in Short Form-12 Questionnaire scores for quality of life (p<0.0001).

Role of Eight-Week Therapy with Ashwagandha Root Extract in Improving Sexual Health in Healthy Men: Findings of a Prospective, Randomized, Double-Blind, Placebo-Controlled Study.

SEXUAL WELLNESS AND TESTOSTERONE IN MEN



300mg/ Twice daily

- A 12.17% and 10.23% increase in Total Testosterone (p<0.001) and Free Testosterone levels respectively.
- A 38.68%, 32.88%, and 38.06% increase in Semen Volume, Sperm Concentration, and Sperm Volume parameters respectively (p<0.001).
- A 160.6% increase in the Level of Sexual Desire scores (p<0.0001).
- The total International Index of Erectile Function domain scores improved significantly (p<0.0001).
- A 44.26% increase in total Short Form-12 Questionnaire scores for quality of life (p<0.0001).

76 Participants

A Prospective, Randomized, Double-Blind, Placebo-Controlled, Clinical Study to Evaluate the Efficacy of KSM-66 Ashwagandha® capsule (300 mg) for Improving Sexual Health in Healthy Men (Under Peer Review).

SEXUAL HEALTH IN WOMEN



- A 60.9% reduction in Female Sexual Distress Scale scores (p<0.001).
- A 62.4%, 59.4%, 82.4%, and 62.4% improvement in Arousal, Lubrication, Orgasm, and Satisfaction domains respectively (p<0.001), and a 75.8% increase in total Female Sexual Function Index scores (p<0.001).
- A 14.3% and 126.1% increase in the Number of Total Sexual Encounters and Successful Sexual Encounters respectively (p<0.001).

Dongre, S., Langade, D., & Bhattacharyya, S. (2015). Efficacy and Safety of Ashwagandha (Withania somnifera) Root Extract in Improving Sexual Function in Women: A Pilot Study. BioMed research international, 2015, 284154.

Participants

SEXUAL WELLNESS AND GENERAL WELL-BEING IN WOMEN



- A 52.8% reduction in Female Sexual Distress Scale scores (p<0.0001).
- A 40%, 48.7%, 75.7%, 71.6%, and 50.8% improvement in Arousal, Lubrication, Orgasm, Desire, and Satisfaction domains respectively, and a 59.2% increase in total Female Sexual Function Index scores (p<0.0001).

- A 18.3% and 31.8% increase in the Number of Total Sexual Encounters and Successful Sexual **Encounters** respectively.
- A 71.03% reduction in total General Health Questionnaire 28 scores.

80 **Participants**

Ajgaonkar A, Jain M, Debnath K. (2022) Efficacy and Safety of Ashwagandha (Withania somnifera) Root Extract for Improvement of Sexual Health in Healthy Women: A Prospective, Randomized, Placebo-Controlled Study. Cureus doi:10.7759/Cureus.

SEXUAL WELL-BEING IN WOMEN



- A 59.24% reduction in Female Sexual Distress Scale scores (p<0.05).
- A 40.23%, 23.65%, 47.21%, 46.78%, 31.45%, and 59% improvement in Arousal, Lubrication, Orgasm, Desire, Satisfaction, and Pain domains respectively, and a 39.28% increase in total Female Sexual Function Index scores (p<0.05).

- A statistically significant increase in the Number of Total Sexual Encounters and Successful Sexual Encounters respectively.
- A 58.06% increase in the Level of Sexual Desire scores and a 37.90% reduction in Perceived Stress Scale scores (p<0.001). **Participants**
 - A 2.17% increase in Estrogen levels and an 18.72% reduction in Follicle Stimulating Hormone levels.

Role of Eight-Week Therapy with Ashwagandha Root Extract in Improving Sexual Health in Healthy Women: Findings of a Prospective, Randomized, Double-Blind, Placebo-Controlled Study.

SEXUAL WELLNESS IN WOMEN



- A 53.67% reduction in Female Sexual Distress Scale scores (p<0.05).
- 58.16%, 64.91%, 81.48%, 43.31%, 62.78%, and 40.31% improvement in Arousal, Lubrication, Orgasm, Desire, Satisfaction, and Pain domains respectively, and a 58.83% increase in total Female Sexual Function Index scores (p<0.05).

- A statistically significant increase in the Number of Intercourses, Orgasms, and Satisfying Sexual Activities respectively.
- A 36.36% increase in the Level of Sexual Desire scores and a 58.02% reduction in Perceived Stress Scale scores.
- A 3.57% increase in Estrogen levels and an 8.16% reduction in Progesterone levels.

A Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Study to Evaluate the Effects of KSM-66 Ashwagandha® capsule (300 mg) on Sexual Health in Healthy Women. (Under Peer review).

Participants

CLIMACTERIC SYMPTOMS IN PERIMENOPAUSAL WOMEN



300mg/ Twice daily The Menopause Rating Scale scores for Psychological and Urogenital domains reduced significantly by 24.7% and 26.67% respectively. There was a 23.51% decrease in the total MRS score (p<0.0001).

8 Weeks The Menopause Specific Quality of Life scores for Vasomotor, Psychological, Physical, and Sexual domains reduced significantly by 2.4%, 5.09%, 5.05%, and 5.09%. There was a 4.02% decrease in the total MEN-QOL score (p<0.0001) respectively.

100

Participants

- A 30.88% decrease in the Hot Flash score (p<0.0001).
- A 35.43% increase in Serum Estradiol levels (p<0.05).
- The levels of Follicle Stimulating Hormone, Luteinizing Hormone, and Testosterone were reduced by 36.60%, 17.27%, and 1.96% respectively.

Gopal, S., Ajgaonkar, A., Kanchi, P., Kaundinya, A., Thakare, V., Chauhan, S. and Langade, D. (2021) Effect of an ashwagandha (*Withania Somnifera*) root extract on climacteric symptoms in women during perimenopause: A randomized, double-blind, placebo-controlled study. *J. Obstet. Gynaecol. Research*, 47(12), 4414-4425.

MENOPAUSAL SYMPTOMS IN WOMEN



300mg/ Twice daily

Participants

- The Menopause Rating Scale scores for Psychological, Somatic, and Urogenital domains reduced significantly by 44.6%, 42.06%, and 31.50% respectively. There was a 40.93% decrease in the total MRS score (p<0.0001).
- A 26.89% decrease in the Number of Hot Flashes (p<0.05).

Wooks

- A 4.5% increase in **Serum Estradiol** levels.
- A 47.01% decrease in Perceived Stress Scale scores (p<0.0001).
- A 90.07% increase in **Short Form-12 Questionnaire** scores, indicating improved quality of life (p<0.0001).

A Prospective, Double-Blind, Randomized, Parallel, Single-Center, Two-Arm, Placebo-Controlled Clinical Study to Assess the Efficacy and Safety of KSM-66 Ashwagandha® capsule (300 mg) on Menopause Symptoms.

HORMONAL HEALTH

THYROID HEALTH



300mg/ Twice daily

- A 8.59% reduction in serum Serum Thyroid Stimulating Hormone concentration (p<0.0001).
- A 47.16% increase in Serum-Free Triiodothyronine (T3) level (p<0.0001).
- A 23.19% increase in Serum-Free Thyroxine (T4) level (p<0.0001).

8 Weeks

50 Participants Sharma, A. K., Basu, I., & Singh, S. (2018). Efficacy and Safety of Ashwagandha Root Extract in Subclinical Hypothyroid Patients: A Double-Blind, Randomized Placebo-Controlled Trial. *Journal of Alternative and Complementary Medicine (New York, N.Y.)*, 24(3), 243–248.

SUBCLINICAL HYPOTHYROIDISM



300mg/ Twice daily

- A significant reduction in Serum Thyroid Stimulating Hormone concentration (p<0.0001).
- An increase in Free and Total Triiodothyronine (T3) levels.
- A decrease in Free and Total Thyroxine (T4) levels.
- A significant decrease in Thyroid Questionnaire Assessment scores (p<0.001).
- A significant improvement in Mini-Mental State Exam scores (p<0.001).

Effects of Ashwagandha Root Extract on subclinical hypothyroidism: A Prospective, Randomized, Placebo-Controlled Study (Under Peer Review).

Weeks

56 Participants

MEMORY AND COGNITION



Participants

- A significant improvement in Working Memory Subtests that relate to the ability to hold information for immediate sequential actions (p<0.05).
- A significant improvement in Executive Function that facilitates coordination, selection, and execution of wilful action (p<0.05).
- A significant improvement in Attention and Processing Speed (p<0.05).
- A significant improvement in General Memory Subtests that relate to the ability to recall after a substantial passage of time, which is associated with learning and productivity (p<0.05).
- A significant improvement in Immediate Memory Subtests that relate to the ability to recall within a few minutes of stimuli presentation and reflect learning ability (p<0.05).

Choudhary, D., Bhattacharyya, S., & Bose, S. (2017). Efficacy and Safety of Ashwagandha (Withania somnifera (L.) Dunal) Root Extract in Improving Memory and Cognitive Functions. Journal of dietary supplements, 14(6), 599-612.

MEMORY, FOCUS, AND COGNITION IN ADULTS



- A significant improvement in Episodic Memory Subtests that relate to the ability to retain memories that can be consciously recorded.
- A significant improvement in Working Memory Subtests that relate to the ability to retain information while carrying out more complex cognitive tasks.
- A significant improvement in Attention and Executive Function (p<0.05).
- A significant reduction of 12.89% in total mood disturbance score on the Profile of Mood States scale (p<0.001).
- The BRIEF-A Scale for Behavior Regulation Index (BRI), and Metacognition Index reduced **Participants**

significantly by 22.34% and 17.03% respectively (p<0.001).

Effects of KSM-66 on cognition, energy, and mood in adults with self-reported, cognitive and energy problems: a randomized, double-blind, placebo-controlled study (Under Peer Review).

MEMORY, FOCUS, AND COGNITION IN CHILDREN



Participants

- A significant improvement in Episodic Memory Subtests that relate to the ability to retain memories that can be consciously recorded.
- A significant improvement in Working Memory Subtests that relate to the ability to retain information while carrying out more complex cognitive tasks.

A significant improvement in Attention and Executive Function (p<0.05).

- An 18.06% reduction in the Strength and Difficulties Questionnaire scores (p<0.05).
- A 14.52% reduction in Sleep Disturbance Scale for Children, indicating improved sleep without disturbance (p=0.04).
- The BRIEF-2 Scale scores for the Behavior at Regulation Index (BRI), Emotional Regulation Index (ERI), and Cognitive Regulation Index (CRI) reduced significantly by 10.98%, 13.14% and 12.84% respectively (p<0.001).

Effects of KSM-66® Ashwagandha on memory, attention, executive function, and sleep in children: a randomized, double-blind, placebo-controlled study (Under Peer Review).

ADHD IN CHILDREN



The ADHD Rating Scale-IV scores for Inattention and Hyperactivity domains reduced significantly by 37.28% and 36.24% respectively. There was a 36.6% reduction in the total ADHD Rating Scale score (p<0.001).

The Behavior Rating Inventory of Executive Function (BRIEF-2) scores for the Behavioral Regulation Index (BRI), Emotional Regulation Index (ERI), and Cognitive Regulation Index (CRI), reduced significantly by 47.9%, 38.7%, and 45.7% respectively. There was a 44.2% decrease in the Global Executive Composite (GEC) score (p<0.0001).

Participants

The Patient-Reported Outcomes Measurement Information System (PROMIS) scores for Sleep Disturbance and Anxiety reduced by 39.5% and 40.9% respectively (p<0.001). There was a 40.1% decrease in the total PROMIS score (p<0.001).

Efficacy of Ashwagandha Root Extract in Treatment of Mild Attention Deficit Hyperactivity Disorder (ADHD) in Children: A randomized, double-blind, placebo-controlled clinical study.

SKIN HEALTH



1ml of skin lotion

- A 55.9%, 66.5%, 86.5%, and 80.5% improvement in Wrinkles, Pores, Hydration, and Pigmentation respectively measured using the Physician Global Assessment scores.
- A 2.82% decrease in the Melanin Index.
- A 15.12% decrease in the Transepidermal Water Loss (TEWL).
 - A 20.6% increase in Skin Hydration.
 - A 16.4% increase in Skin Elasticity.

53 Participants Narra K, Naik S K, Ghatge A S (March 15, 2023) A Study of Efficacy and Safety of Ashwagandha (Withania somnifera) Lotion on Facial Skin in Photoaged Healthy Adults. Cureus 15(3): e36168. doi:10.7759/cureus.36168.

HAIR HEALTH



2ml of hair serum A 45.08% and 68.87% reduction in hair loss was seen in both Hair with Bulb Count and Hair without Bulb Count respectively.

75 Days A 4.64%, 7.28%, 3.55%, and 4.83% improvement in Hair Density, Hair Growth, Hair Thickness, and Anagen Percentage. Also, there was an 8.33% reduction in the Telogen Percentage and an overall reduction of 51.75% in the Anagen and Telogen Ratio (A:T ratio).

A 68.88% decrease in the Percentage of Hair Pulled.

60 Participants The Hair Specific Skindex-29 scores for Symptom scores, Function scores, Emotional scores, and Total scores were reduced significantly by 16.81%, 21.14%, 12.49%, and 17.82% respectively.

Yerram, C., Jillella, A., & Reddy, V. (2023). Effects of *Withania somnifera* root extract serum application on hair health in healthy adults: A prospective, double-blind, randomized, parallel, placebo-controlled study. *Journal of Ayurveda and Integrative Medicine*, 14(6), 100817. https://doi.org/10.1016/j.jaim.2023.100817.

HAIR AND SKIN HEALTH (ORAL ADMINISTRATION)



300mg/ Twice daily

- A 11.80% decrease in Transepidermal Water Loss (TEWL).
- A 11.73% decrease in Dermatology Quality of Life Index (DLQI) scores.
- A 3.47%, 4.62%, and 3.86% improvement in Hair Density, Hair Growth, and Anagen Percentage respectively. Also, there was a 15.63% reduction in the Telogen Percentage.

• The Hair Specific Skindex-29 scores for Symptom scores, Function scores, Emotional scores, and Total scores were reduced significantly by 18.98%, 23.40%, 17.70%, and 20.31% respectively.

100 Participants A Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Study of Efficacy and Safety of Ashwagandha Root Extract Capsule on Skin and Hair Health in Healthy Adults (Under Peer Review).

SAFETY OF KSM-66 ASHWAGANDHA



300mg/ Twice daily

- No statistically significant change or abnormality in the Thyroid Hormonal Profile.
- No significant change in Alanine Transaminase (ALT/SGPT), Aspartate Transaminase (AST/SGOT), and Alkaline Phosphatase.
- No statistically significant change in the respective mean values of Hematological Parameters and Vital Parameters.

Verma, N., Gupta, S. K., Tiwari, S., & Mishra, A. K. (2020). Safety of Ashwagandha Root Extract: A Randomized, Placebo-Controlled, Study in Healthy Volunteers. *Complementary therapies in medicine*, 57, 102642.

80 Participants

ANTI-AGING

LIFESPAN EXTENSION OF CAENORHABDITIS ELEGANS



- Purpose: To evaluate the effect of KSM-66 Ashwagandha in enhancing the lifespan of Caenorhabditis elegans.
- Results: Wild-type worms showed around 20% Lifespan Extension when treated with KSM-66 Ashwagandha. The authors concluded that KSM-66 Ashwagandha successfully enhanced the lifespan of C. elegans.

Kumar, R., Gupta, K., Saharia, K., Pradhan, D., & Subramaniam, J. R. (2013). Withania somnifera root extract extends lifespan of Caenorhabditis elegans. Annals of neurosciences, 20(1), 13-16.

TELOMERASE ACTIVITY IN HELA CELLS



- Purpose: To evaluate the effect of KSM-66 Ashwagandha to increase telomerase activity in HeLa cells, an in-vitro human cell-culture model.
- Results: KSM-66 Ashwagandha increased Telomerase Activity. Thus, ashwagandha root extract has anti-aging potential.

Raguraman, V. and Subramaniam, J. (2016) Withania somnifera Root Extract Enhances Telomerase Activity in the Human HeLa Cell Line. Advances in Bioscience and Biotechnology, 7, 199-204.

TOXICITY STUDIES ON KSM-66 ASHWAGANDHA



- Acute Oral Toxicity of KSM-66 Ashwagandha in Rats.
- 28-day Repeated Oral Dose Study of KSM-66 Ashwagandha in Rats.
- Acute and 28 Days Repeated Dose Genotoxicity Study of Ashwagandha in Albino Rats.
- Acute Oral Toxicity Study of KSM-66 Ashwagandha Root Extract in Wistar Rats.
- Two weeks Dose Range Finding Study of KSM-66 Ashwagandha Root Extract by Oral Route in Wistar Rats.
- 90-Day Repeated Dose Oral Toxicity Study Of KSM-66 Ashwagandha Root Extract in Wistar Rats.
- In vivo Mammalian Erythrocyte Micronucleus Test with KSM-66 Ashwagandha Root Extract in Swiss Albino Mice.
- Bacterial Reverse Mutation Test with KSM-66 Ashwagandha Root Extract in Salmonella Typhimurium Strains.
- In vitro Chromosomal Aberration Test with KSM-66 Ashwagandha Root Extract in Cultured Human Lymphocytes.
- Thyroid Toxicity Evaluation in Zebrafish Embryos.
- Subacute Toxicity of KSM-66 Ashwagandha in Rats.
- Reproductive and Developmental Toxicity of KSM-66 Ashwagandha in Rats.

STRESS AND IMMUNITY IN HORSES



2.5g, 5g, or 10g/animal

- A statistically significant reduction (p<0.05) in the Cortisol and Epinephrine levels.
- A statistically significant increase in Super Oxide Dismutase concentration (p<0.05).
- A non-significant increase in Total Eryhrocyte Count, Total Leucocyte Count, Hemoglobin, and Lymphocyte Percentage.

21 Days A statistically significant decrease in Glucose, Triglycerides, Creatinine, Alanine Aminotransferase, Aspartate Aminotransferase, and Interleukin-6 concentrations (p<0.05).

24 Animals Priyanka G, et al B (2020). Adaptogenic and Immunomodulatory Activity of Ashwagandha Root Extract: An Experimental Study in an Equine Model. *Frontiers in Veterinary Sciences* 7:541112.

STRESS AND ANXIETY IN DOGS



15mg/kg body weight

- A 26.9% reduction in Urine Cortisol Creatinine ratio (p<0.001).
- A 44.4% and 42.2% reduction in Canine Brief Pain Inventory scores for Pain Severity and Pain Interference respectively.
- A 19.5%, 36.0%, and 20.5% reduction in the Fear and Anxiety, Excitability, and Aggression domains of the Canine Behavioral Assessment & Research Questionnaire scores.

Kaur J, Seshadri, S, Golla, K & Sampara, P (2022) Efficacy and safety of standardized Ashwagandha (*Withania somnifera*) root extract on reducing stress and anxiety in domestic dogs: A randomized controlled trial. *Journal of Veterinary Behavior*, 51, 8-15.

STRESS AND ANXIETY IN CATS



15mg/kg body weight

- A statistically significant increase in Erythrocyte Count, Leucocyte Count, and Hemoglobin (p<0.05).
- A statistically significant increase in Catalase, and GSH concentrations (p<0.001).
- A significant reduction in Cortisol levels (p<0.05).
 - A significant decrease in the Tumour Necrosis Factor-α, Interferon-γ and Interleukin-10 concentrations.

16 Animals Efficacy and safety of KSM-66 Ashwagandha in reducing stress and anxiety and in improving the general well-being in cats (Under Peer review).

AGING-RELATED CHANGES IN HEALTHY GERIATRIC DOGS



body weight

- A statistically significant increase in Erythrocyte Count, Leucocyte Count, and Hemoglobin (p<0.05).
- A statistically significant increase in Super Oxide Dismutase, Catalase, and GSH concentrations (p<0.001).
- A 21.6% reduction in Cortisol levels.
- A statistically significant reduction in Interferon-γ and Interleukin-10 concentrations (p<0.001).

20 Animals Effects of Ashwagandha Root Extract on Aging-Related Changes in Healthy Geriatric Dogs: A Randomized, Double-Blinded Placebo-Controlled Study (Under Peer review).

HEALTH CANADA CLAIMS



Health Canada has granted approval to KSM-66 for a broad range of compelling functional claims based on KSM-66's impressive set of clinical studies, which have been published in respected peer-reviewed journals indexed in the PubMed database of the U.S. Government's NIH. Under Health Canada NPN (Natural Product Number) 80047973, a few of the end-product claims that formulators can make using KSM-66 at the clinically relevant dosage are:

- Helps increase resistance to stress/anxiety in individuals with a history of chronic stress, thereby improving their overall quality of life.
- 2. Athletic support or Workout/ Exercise supplement.
- Helps promote healthy testosterone production in males.
- Helps support physical aspects of sexual health in women.
- 5. Used in herbal medicine for memory enhancement.
- Used in herbal medicine as Rasayana (rejuvenating tonic);
- Used in herbal medicine to relieve general debility, especially during convalescence and old age.

- 8. Used in herbal medicine as a sleep aid.
- Used in herbal medicine as an adaptogen to help increase energy and resistance to stress.
- 10. Helps support libido.
- 11. Helps support emotional aspects of sexual health.
- 12. Helps support thyroid function in people with hypothyroidism.
- Helps in the function of the thyroid gland in people with hypothyroidism; and
- Helps promote physical performance in previously untrained individuals when combined with regular resistance training.

STUDIES UNDER PEER REVIEW

- 1. Efficacy and safety of KSM-66 Ashwagandha root extract on Stress and Stress-related food cravings.
- 2. Efficacy and Safety of KSM-66 Ashwagandha for Menopausal symptoms in women.
- 3. Efficacy and Safety of KSM-66 Ashwagandha root extract in the management of Frailty in Older Adults.
- 4. Efficacy and Safety of KSM-66 Ashwagandha root extract on Immune Function Enhancement and Quality of Life in Healthy adults.
- 5. Efficacy and Safety of KSM-66 Ashwagandha root extract administration on the improvement of Skin and Hair Health parameters in Healthy adults.
- 6. Efficacy and Safety of the Topical Application of Serum containing KSM-66 Ashwagandha root extract on Hair Health parameters in Healthy adults.
- 7. Efficacy and Safety of the Topical Application of Lotion containing KSM-66 Ashwagandha root extract on Skin Health parameters in Healthy Adults.
- 8. Efficacy and safety of KSM-66 Ashwagandha root extract in improving Cognition in Dogs: A Randomized, Place-bo-controlled, Multicentric study.
- 9. Efficacy and safety of KSM-66 Ashwagandha root extract in improving Endurance in Horses: A Randomized, Place-bo-controlled, Multicentric study.

ONGOING STUDIES

- Stress and Anxiety (Multicentric, 1200 participants across 7 countries) 1
- Men's Health 1
- Women's Health 1
- High Dose Safety 1
- Sleep 1
- Personal Care (Hair, Skin, Beauty from outside, Beauty from within) 3
- Long-term Safety 1
- Children 1
- Pet Health 2
- Stress and Anxiety 2

SUBSTANTIATED STRUCTURE/FUNCTION CLAIMS

KSM-66 Ashwagandha's substantiated structure/ function claims are in accordance with the requirements of the Dietary Supplement Health and Education Act of 1994. Backed by peer-reviewed studies, numerous claims have been deemed acceptable for KSM-66. Some examples include:

Stress and Anxiety Sleep Helps to reduce stress and anxiety. Helps to improve the quality of sleep. Helps to promote calming and relaxation. Helps to reduce sleep onset latency. Helps to reduce and maintain normal cortisol levels. Helps to boost sleep efficiency. Helps to reduce mood disturbances and elevate your Helps to enhance mental alertness on rising. Helps to wake up fresh. Helps to promote happiness. **Memory and Cognition: Sports Function** Helps to boost stamina and endurance. Helps to improve memory and cognition. Helps to increase muscle size. Helps to boost executive function and attention. Helps to increase muscle strength. Helps to enhance mental focus and mental clarity. Helps to reduce body fat percentage. Helps to retain information and memories. Helps to reduce fatigue and enhance sports Helps to improve speed and accuracy of mental performance. performance. Helps to increase the speed of muscle recovery. Men's Health: Women's Health: Helps to increase and maintain healthy levels of Helps to reduce sexual distress. natural testosterone. Helps to increase sexual arousal, lubrication, orgasm Helps to increase sexual desire, drive, arousal, and and satisfaction. satisfaction. Helps to enhance sexual desire and overall sexual Helps to improve sexual performance and overall function. Helps to alleviate menopausal symptoms. sexual health. Helps to increase sperm count, sperm concentration, Helps to reduce hot flashes and night sweats. Helps to support a healthy response to common and semen volume. symptoms associated with menopause. **Weight Management: Thyroid Function Support** Helps to curb stress-related eating habits. Helps to normalize thyroid hormone levels. Helps to reduce food cravings. Helps to maintain normal thyroid health. Helps to improve overall body composition when used as a part of a healthy diet and exercise program. **Children: Personal care:** Helps to improve sleep. Helps to improve skin hydration and skin texture. Helps to reduce inattention and hyperactivity in Helps to reduce hyperpigmentation and boost collagen production. Helps to improve behavior and emotional regulation. Helps to improve hair density and reduce hair fall. Helps to improve memory, learning, concentration, Helps to nourish the scalp and reduce scalp irritation. and focus.

The above statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. These claims are based upon clinical studies. It is the responsibility of the manufacturer (licensee) to notify the FDA within 30 days, after first marketing a product with a structure/function claim that the statement(s) are being made, as required under section 403(r)(6) of the FD&C Act.



WORLD'S BEST ASHWAGANDHA

FROM THE ASHWAGANDHA EXPERTS. THAT'S ALL WE DO.

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