Safety, Efficacy and In-Use Tolerability Study of Phyto-Nutraceutical Supplements

NovoBliss® Research

Background: Insomnia is the perception or complaint of inadequate or poor quality of sleep because of difficulty in falling asleep, difficulty in maintaining sleep or waking too early in the morning. Poor sleep and sleep deprivation have been associated with poor concentration, poor judgment, depression poor decision-making skill. The test treatment allows to get a deep sleep, so person can wake up energized, rested and refreshed for the day ahead. A good quality sleep is very important for good health.

Aims/Objective: To evaluate safety, efficacy, and in-use tolerability of phyto-nutraceutical supplements in healthy adult human subjects having difficulty to fall asleep.

Materials/Methods: This was a single-arm, single-blind, subject blinded, clinical safety, efficacy and in-use tolerability study. A total of 35 subjects ages 18 to 65 years were enrolled, and 32 subjects completed the study. The duration of the study was 5 weeks with 1 week of pre observational period, 2 weeks of treatment period and 2 weeks of post observational period with total of 4 visits. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and are consistent with ICH/GCP guidelines. The study was approved by Ethics Committee and registered at Clinical Trial Registry of India and Clinicaltrials.gov.

Results: The test treatment was evaluated for change in sleep quality, duration of sleep, improvement in overall health and well-being. There was 3X improvement observed in the quality of sleep from the baseline Day 01 to Day 15 after test treatment usage. There was 1.3X improvement in total hours of sleep observed as reported by the subjects. After completion of test treatment for 15 days, it was found that 100% of the subjects fall asleep within 30 minutes after going to bed. There was an 6X improvement in time interval to fall asleep after going to bed as reported by subject. The test treatment was also evaluated for dependence and withdrawal symptoms post stopping the test treatment. None of the subjects reported any craving for taking a test treatment, felt habituated about the test treatment, felt nausea, vomiting, headache, dizziness, anxiety, or stress after stopping the test treatment usage at Day 30.

Conclusion: As per the Investigator, the test treatment was found to be efficacious in healthy human adult subjects (18 – 65 years) with 100% well-being. After analysis of the various effective parameters, our results clearly revealed that the test treatment has significantly improved the quality of sleep by 3X times leading to improvement in giddiness, heaviness in the head, headache, exhaustion, yawning, drowsiness, lack of concentration, mental fatigue and fatigue with no craving for taking a test treatment, felt habited about the test treatment, felt nausea, vomiting, headache, dizziness, anxiety, or stress after stopping the test treatment usage. No clinically significant changes or adverse events occurred or were felt due to the test treatment during the trial period.

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