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Studies on the effectiveness and safety of anti hangover drink (Oh!K) in reducing cocktail (alcohol) induced hangover symptoms in adult male social drinkers

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ABSTRACT
The 'hangover' by using alcohol is associated with variety of physiological symptoms like headache, fatigue, nausea etc. The cause of alcohol hangover is due to the production of toxic chemicals and free radicals during the course of alcohol metabolism. The loss of water and minerals from the body also contributes its part. The hangover symptoms were observed large extend when the drinks were consumed as cocktails. A natural spice blend was developed, branded as Oh!K and evaluated clinically for its efficacy. Alcohol induced hangover symptoms such as tremor, headache nausea were observed and experienced by the subjects on the day following the consumption of alcohol as cocktail. This was shown to be significantly reduced in the volunteers who had consumed Oh!K Anti Hangover drink (50 ml) after consuming alcohol-cocktail. The hangover symptom of tremor was significantly reduced only in the subjects who has consumed 50ml – high dose of Oh!k Anti Hangover Drink.

Keywords: Hangover, cocktail, spice blend, tremor

1. Introduction
An alcohol hangover is associated with a variety of symptoms that may include drowsiness, concentration problems, dry mouth, dizziness, gastrointestinal complaints, fatigue, sweating, nausea, hyper-excitability, anxiety and a feeling of general discomfort that may last more than 24 hours. When the body metabolizes alcohol, it creates a chemical called acetaldehyde, which is then broken down by enzymes in your body. After the body runs out of acetaldehyde busters, the acetaldehyde starts to build up, making the body feel terrible longer by exacerbating the other symptoms. Acetaldehyde, the first by-product of ethanol, is between 10 and 30 times more toxic than alcohol itself. In addition, certain genetic factors can amplify the negative effects of acetaldehyde [1]. For example, some people (predominantly East Asians) have a mutation in their alcohol dehydrogenise gene that makes this enzyme unusually fast at converting ethanol to acetaldehyde. Generally it was observed that a mixture of drinks i.e., cocktails will increase the hangover symptoms than a single drink.

2. Materials and methods
The drink was formulated using the spice extracts such as green ginger, turmeric, pepper, and green tea extract, along with salt, citric and ascorbic acid. Fructose was used as the carrier.

2.1 Methodology
The purpose of the study was to evaluate the effectiveness, safety and tolerability of 50 ml of Oh!K Anti Hangover Drink in reducing the cocktail alcohol induced hangover symptoms in adult male social drinkers. The clinical study was planned, designed, conducted and reported as per applicable ethical and regulatory guidelines – ICH Tripartite Guidelines – E6 (R1)-Good Clinical Practice, Indian Council of Medical Research's (ICMR) Ethical Guideline for Biomedical Research on Human Participants. Prior to conduction, the clinical study was reviewed and approved by an Ethics Committee. The study was also registered with ICMR's Clinical Trial Registry India and World Health Organisation (WHO) – International Clinical Trial Registry Platform. Volunteers were pre screened at hotels, bars, pubs and other alcohol selling outlets. Six such volunteers who were identified as occasional consumers of alcohol (social drinkers) were further screened as per the norms of the approved study protocol. The

Screening Questionnaires such as Short Michigan Alcohol Screening Test (SMAST) and Modified Suicide Behaviors Questionnaire (m-SBQ) were answered by participants [2]. The drinking pattern of participants in past 12 months was assessed through Subjective Questionnaire Short Michigan Alcohol Screening Test (SMAST). The suicidal behaviors of study participants were assessed by the principal investigator through Objective Questionnaire Modified Suicide Behaviors Questionnaire (m-SBQ). For baseline metrics, objective and subjective measurements using CIWA – A (Clinical Institute Withdrawal Assessment -Alcohol) and m-AHSS (Alcohol Hangover Severity Scale) for alcohol induced hangover symptoms such as tremors, headache, nausea, cognitive, auditory and visual impairment etc were assessed.

2.2 Objective assessment

CIWA-A Questionnaire was measured by Social Scientist/Psychologist or by Principal Investigator and the subjective assessment was measured using m-AHSS on Day 1 (enrollment and before consumption of alcohol) and Day 2 (hangover day) to assess the hangover symptoms. Metered dose of alcohol cocktail was calculated as per the body weight category and provided to each subject along with dietician approved food. Post consumption of cocktail, the alcohol concentration was measured using an Alcohol Breath Analyser. 50 ml of Oh!K Anti Hangover Drink was then provided to the subjects based on the randomisation schedule. The subjects were allowed to sleep for a period of 10 hours. Upon waking up, a sleep inertia time of 30 minutes was allowed. The objective and subjective questionnaires CIWA-A and m-AHSS were assessed and data was recorded. The volunteers were constantly monitored by an attending physician and the entire study was conducted by checking in the subject in the research facility. This negates any external influences of food/drug or uncontrolled consumption of alcohol that may have influenced the study [3-4].

Safety investigations such as Complete Blood Count and Serum Biochemistry and recording of vital signs such as body temperature, blood pressure, respiratory rate and pulse rate were also measure on day 1 and day 2 to ensure safety of the subjects. The subjects were also constantly monitored during Day 1 and Day 2 of Visit 1 for adverse events. None of the subjects were reported/observed any adverse Events. The subjects were checked out after getting written clearance from the principal investigator. The Laboratory Results of Blood Investigations (Complete Blood Count and Serum Biochemistry - Liver Function Test and Renal Function Test) made at the end of study were also found as normal and within-range for all subjects.

3. Results and Discussion

3.1 Efficacy Results

The objective and subjective questionnaires Clinical Institute Withdrawal Assessment – Alcohol (CIWA-A) and Modified Alcohol Hangover Severity Scale (m-AHSS) were used to assess the Hangover symptoms during Day 1 of Visit 1 (before alcohol consumption) and Day 2 of Visit 1 as efficacy measurements.

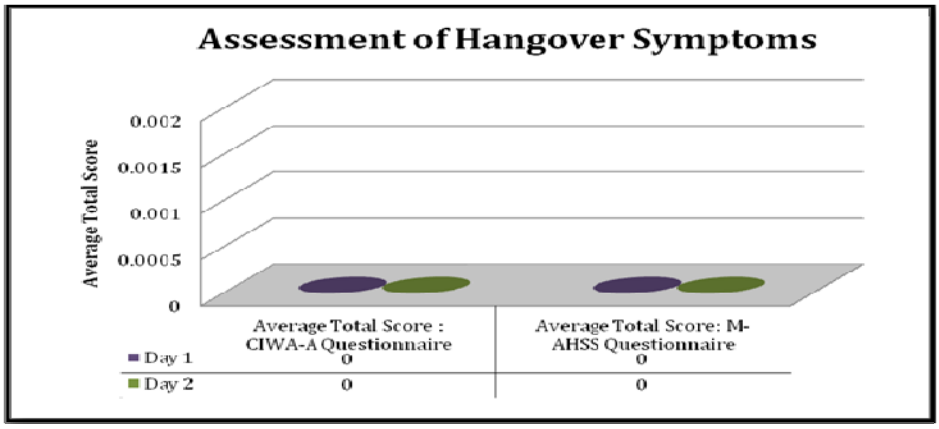

Fig 1: Assessment of hangover symptoms.

Alcohol Free day (Day 1 of Visit 1)

Mean (SD) Total Score of CIWA- A questionnaire – 0 (0)
Mean (SD) Total Score of m-AHSS questionnaire - 0 (0)

Hangover day (Day 2 of Visit 1)

Mean (SD) Total Score of CIWA- A questionnaire – 0 (0)
Mean (SD) Total Score of m-AHSS questionnaire - 0 (0)

The above results show that no change was observed in Total score of CIWA-A and m-AHSS Questionnaire from Day 1 to Day 2 of Visit 1.

None of the subjects experienced any hangover symptoms on in previous day.

4. Conclusion

With regard to the Hangover Symptoms measured by Clinical Institute Alcohol Withdrawal – Alcohol (CIWA-A) questionnaire and Modified Alcohol Hangover severity scale (m-AHSS), the end points were achieved. The Hangover symptoms were completely nullified on next day of cocktail consumption due to the consumption of Anti Hangover Drink Hence it is recommended that Anti Hangover Drink (50 ml) next day morning of cocktail consumption (Day 2 of Visit 1). This zero score on Hangover Day signifies that the Hangover symptoms were completely nullified by Anti Hangover Drink (50 ml) and making it similar to Alcohol free day [5].

can be taken to reduce next day Alcohol Hangover Effects even for Cocktails.

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