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Instant energy stimulant nutraceutical cube formulation: Low endothermic promoting booster milk drink

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***Abstract*---**The need for innovative study and formulation is praised from the claim of those occupational personnel including software Engineers, those who get tremendously tired after their office work 9:00am -05:00pm. That time tea/coffee/health drinks won't work with many pros and cons because it takes a long time to prepare and to initiate action, sometimes addiction, its lengthy preparation and blending processes and single mild stimulation drug efficiency. The method development and preparation of a formulation processing the cumulative effects of CNS stimulant, effective natural vasodilatation, energy boosting to brain, normalize function of immune system to reduce tiredness and fatigue, as brain tonic with caffeine dust,

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Theobroma Cacao dust, glucose/sucrose, vitamin –C, Brahmi's leaf extract respectively. These components were in the form of solid cubes formulation with dispersible deliquescent additives of sodium citrate. Thus, get soluble in a low temperature 60-70°C of Luke warm liquid medium for drinks. These low temperature instant-energy boosters take less time to prepare and avoid thermo-labile constituent's degradation. This formulation acts as multifactor benefits to the volunteers as instant stimulation and steady energy–brain tonic along with zero recurrent hangovers. Results have been observed in 30 volunteers that after continuous consumption disappeared the feeling intensity of tiredness and fatigue.

***Keywords*---**CNS Stimulant without side effect, ease & fast preparation, nutraceutical cube formulation, novel steady energy-brain tonic.

Introduction

The Central nervous system (CNS) stimulants were only used to re-energize and initiate freshness to the personnel working in the office mentally [1]. CNS stimulants used for low attention problem, narcolepsy [2-3] attains amphetamines [4], atomoxetine, methylphenidate, armodafinil, modafinil, pitolisant and solriamfetol etc. Now a day's stimulant is not relevant to its perfect efficiency [5]. Some study shows the strychnine-or caffeine-induced tonic extensor seizures [6]. Even CNS stimulants have hypothesized clinical efficacy for enhancing functional consequences in schizophrenia patients, and where further study should be organized for its randomised clinical trials [7]. Many energy revitalizing drugs like *Withania somnifera (WS*) have been working in the market [8]. But, none of them is safer, without addiction & habituation, stable to its effects without recurrence of tiredness and fatigue hangover. Though it's not devoid from their chronic withdrawal symptoms. An innovative work has been done after getting through clinical study.

Methodology

Need is arise to focus on the proper designing of the composition & formulation to process the cumulative effects through all dimensions without any certain side effects.

Designing of formulation

While going to formulize the nutraceutical products the total activities of the drugs composition has to be on consideration. Just like, low dose of natural stimulant, average vasodilators, antioxidant, inflammation marker, brain tonicity, energy boosting to cerebral tissues, normal functioning of immune system regulator. So, the composition and its characteristics evaluation could be readily meant for the nutraceutical dosage Cube. Also, highly dissolution on low enthalpy and lukewarm milk temp of 60°C means to avoid component quality degradation.

Table-1
Validated compositions and its activity and safety concerns.

Sl.No.	Composition/ ingredients	Quantity	Pharmacological Effects/ Activity	Drug Interaction (DI)	Adverse Drug Reaction
1	Caffeine dust	40 mg	CNS stimulant, vasodilator	No DI	No ADR
2	10% Theobroma Cacao dust	20 mg	Antioxidant, increase Nitric oxide as vasodilator	No DI	No ADR
3	Vitamin C powder	400mg	Normal immune system regulator	No DI	No ADR
4	Brahmi extract	45 mg	Increase brain alertness and quick pick-ups	No DI	No ADR
5	Sucrose	7gm	Increase glucose level high calorie for brain	No DI	No ADR
6	Tri-Sodium Citrate	100mg	Dispersing agent increase water solubility	No DI	No ADR

Protocol

A) Preparation: The required amount of caffeine dust mixed with powdered sucrose on equal proportions in pastel mortar. After that required 10% Theobroma Cacao dust was weighed and mixed with equal proportion of fresh sucrose powder the same way. Brahmi's extract, which was previously extracted with alcohol and in crystal form after lyophilized drying, has been ground and powdered. This anhydrous dried powder is allowed to mix with the total triturated mass of sucrose. Thereafter, the required amount of Vitamin C and Tri-Sodium Citrate was triturated with the total triturated powder mixture of blended Sucrose. Gradually, the remaining sucrose were triturated with the total sucrose blended mass in 1:1 ratios.
B) Dosage design: The total mass of the blended powder here need to be compress without hydration. The Cocoa butter dust, caffeine dust with sucrose will acts as a best natural binder. The total mass should be stored with silica gel. Thus, the blended mass was compressed to a cube block (Figure-1) with specific dies of dimensions of 2.7cm*2.7cm*2.7cm (Length*Breath*Height). The compression machine is locally designed in Bangalore as per the Figure-2. Just we need to dissolve the DISPERSIBLE cube in lukewarm 250 ml milk upto 60°C. Within 2 min. the stimulant energy safe drink will ready.

Figure-1: The compressed nutraceutical formulated cube dosage of low enthalpy booster drink

Figure-2: Formulated Cube compressed machine.

Clinical Evaluation: This is clinically tested on 11 volunteers from July, 2020 to till now with its follow-up reports (Table-2). As this is not having any new unknown drug analogs and most of the ingredients are a part of confectionaries and safety established as per the dose is concern. So, no ethical committee permission is required. Here all volunteers are healthy volunteers and do not complain of any diseases like no neuro, no Gastrointestinal, no diabetes, no addict, no hematological problems, no nephro and no Cardiovascular patient. Patients are all age limit between 25-45 years, Males, Indian ethnic and office occupational body weight between 50-65 Kg.

Table-2
Clinical improvement from the drowsiness, fatigue and tiredness with increase alertness

Volunteer's occupation	Intensity of drowsiness before Drink	Dosing of booster drink	Biochemistry Report (least)	Tendency addiction /habituation	Degree /score of improvement in alertness after1 month	ADR Reported
Software Engg	Avg. After 6hrs of work	1 cube OD	COVID +ve	No habituation even after 1 month	10hrs alert no intense drowsy	No ADR
Software Engg	Avg. After 8hrs of work	1 cube OD	Bilirubine high	No habituation even after 1 month	11hrs alert no intense drowsy	No ADR
Software Engg	Avg. After 7hrs of work	1 cube OD	Normal	No habituation even after 1 month	12hrs alert no intense drowsy	No ADR
Assoc. Professor	Avg. After 9hrs of work	1 cube OD	High SGOT	No habituation even after 1	14hrs alert no intense drowsy	No ADR

				month		
Asst. Professor	Avg. After 8hrs of work	1 cube OD	Normal	No habituation even after 1 month	10hrs alert no intense drowsy	allergy
Insurance agent	Avg. After 12hrs of work	1 cube OD	High BUN	No habituation even after 1 month	16hrs alert no intense drowsy	No ADR
Nursing	Avg. After 7hrs of work	1 cube OD	Normal	No habituation even after 1 month	11hrs alert no intense drowsy	No ADR
businessman	Avg. After 12hrs of work	1 cube OD	High Serum Creatinin	No habituation even after 1 month	13hrs alert no intense drowsy	No ADR
Sports person	Avg. After 7hrs of work	1 cube OD	Normal	No habituation even after 1 month	09hrs alert no intense drowsy	No ADR
Dietician	Avg. After 7hrs of work	1 cube OD	WBC Less	No habituation even after 1 month	10hrs alert no intense drowsy	No ADR
Clinician	Avg. After 8hrs of work	1 cube OD	COVID +ve	No habituation even after 1 month	11hrs alert no intense drowsy	Oneday3hrs insomnia

Result & Discussion

The intensity of the drowsiness and score of improvement in alertness after 1 month was comparatively analyze to see the correlation (Pearson Correlation coefficient) Table-3 indicate the R is 0.8052 and R^2, the coefficient of determination, is 0.6483; The P-Value is 0.002785, significance. Linear Regression Y= 0.83032 + 4.67647.

Table-3
Pearson correlation coefficient statistical calculation to find R^2 and P-Value

X value	Y value	Y- M_y	$(X-M_x)^2$	$(Y-M_x)^2$	$(X-M_x)$	$(Y-M_y)$
6	10	-2.273	-1.545	5.165	2.388	3.512
8	11	-0.273	-0.545	0.074	0.298	0.149
7	12	-1.273	0.455	1.620	0.207	-0.579
9	14	0.727	2.455	0.529	6.025	1.785
8	10	-0.273	-1.545	0.074	2.388	0.421
12	16	3.727	4.455	13.893	19.843	16.603

7	11	-1.273	-0.545	1.620	0.298	0.694
12	13	3.727	1.455	13.893	2.116	5.421
7	9	-1.273	-2.545	1.620	6.479	3.240
7	10	-1.273	-1.545	1.620	2.388	1.967
8	11	-0.273	-0.545	0.074	0.298	0.149
		Mx: 8.273	My: 11.545	Sum: 40.182	Sum: 42.727	Sum: 33.364

X Values | *X and Y Combined* | *R Calculation*

$\sum = 91$

Mean = 8.273

$N = 11$

$\sum(X - M_x)(Y - M_y) = 33.364$

$r = \sum((X - M_y)(Y - M_x)) / \sqrt{((SS_x)(SS_y))}$

$\sum(X - M_x)^2 = SS_x = 40.182$

$r = 33.364 / \sqrt{((40.182)(42.727))} = 0.8052$

Y Values | *Meta Numerics (cross-check)*

$\sum = 127$

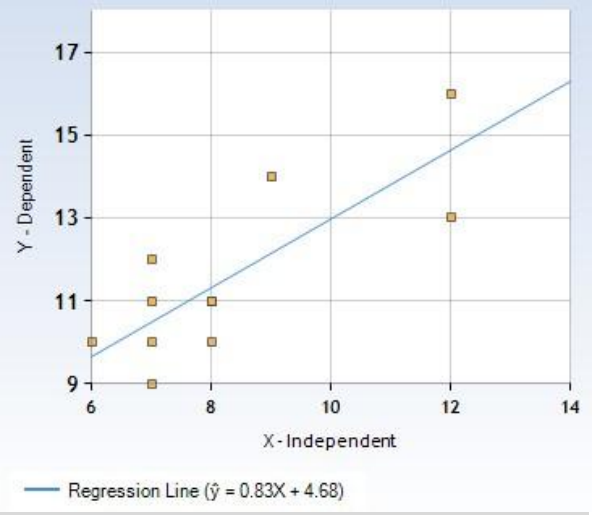
Mean = 11.545

$r = 0.8052$

$\sum(Y - M_y)^2 = SS_y = 42.727$

The value of R is 0.8052. This is a strong positive correlation, which means that high X variable scores go with high Y variable scores (and vice versa).The value of R^2, the coefficient of determination, is 0.6483. The P-Value is 0.002785. The result is significant at $p<0.05$.

Linear Regression



$\hat{y} = 0.83032X + 4.67647$

Statistical Report

The statistical reports say the One Way ANOVA of both the column the intensity of the drowsiness and score of improvement in alertness after 1 month. The Mean of Square 58.9091, degree of freedom is 1 (Between treatment); 4.1455, degree of freedom is 20 (Within treatment); F= 14.21053, The t-ratio value is 14.21053. The

P-Value is 0.001205. The result is significant at $p<0.05$. Thus, its clear proof that the drug improvement to the individual has significantly happened and no its clear-cut no recurrence, no addiction, no dependence. Clinically, the volunteers are neither getting the dependency of drink nor withdrawal symptoms after 1 month of treatment. Also, the freshness and energetic activity remains hours longer with improvement and has been extended with longer treatment upto 1 year.

Conclusion

This innovative discovery confirmed that the nutraceutical product cube formulation opens the cerebral vasculature along with antioxidant supply, maintains the normal immune regulation, quick concept pick-up (presence of mind), CNS stimulation and quick glucose enriches the brain. And also disperse readily without time taking in low boiling temperature. This formulation is non habitual, slowly improves the alertness time and decreases the intensity of drowsiness, fatigue and tiredness forever. It's a stable improvement in stamina independent of dose.

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