CLINICAL STUDY REPORT

"SLIMMING TEA"

Manufactured by

Tea Experts India Private Limited

Protocol No.: CS/TAAB/2017/01

Dated: 17/01/2017

CLINICAL STUDY REPORT	
Study Title	A single-centric, open level, single-arm, non-comparative, prospective clinical study to assess efficacy and safety of Slimming Tea manufactured by Tea Experts India Private Limited in reducing weight in overweight and/or obese adults
Protocol No	CS/TAAB/2017/01 Dated: 17/01/2017
IP	Slimming Tea manufactured by Tea Experts India Private Limited
Study Initiation Date (first patient enrolled)	29/01/2017
Study Completion Date (last patient completed)	21/04/2017
Design	Single-centric, open level, single-arm, non-comparative, prospective study Duration: 3 months Number of patients: 150 No. of Groups: 5
Patient Allocation	Total hundred and fifty patients were allocated into the five treatment group as per protocol (30 patients in each group).

Principal Investigator	**Study Coordinator**
24/05/17 **Dr. Debashis Deb** **MBBS, M. S. FIAMS** **Reg. No. - 61329 WBMC**	24/05/2017 Prof. (Dr.) T. K. PAL FIE, VDI (Germany) Former DAAD Fellow (Germany) Technical Advisor TAAB BIOSTUDY SERVICES 27, Central Road, Kolkata - 700032
Dr. Debashis Deb, MBBS, MS Consultant, TAAB Biostudy Services TAAB Biostudy Services 69, Ibrahimpur Road, Kolkata-700032 taab_bio@yahoo.com	**Prof. (Dr.) T. K. Pal** Technical Advisor TAAB Biostudy Services 69, Ibrahimpur Road, Kolkata-700032 taab_bio@yahoo.com

Compliance statement: This study will be performed in compliance with ICH E6R1 "Guidance on Good Clinical Practice", Indian Good Clinical Practices Guideline, Schedule Y, ICMR Guidelines, Declaration of Helsinki and relevant SOPs of Tea Experts India Private Limited.

This clinical study report was prepared in accordance to the International Conference on Harmonization (ICH) Harmonized Tripartite Guideline E3: Structure and Content of Clinical Study Reports, 30 Nov. 1995 and Schedule 'Y'

STUDY SYNOPSIS	
Study Title:	A single-centric, open level, single-arm, non-comparative, prospective clinical study to assess efficacy and safety of Slimming Tea manufactured by Tea Experts India Private Limited in reducing weight in overweight and/or obese adults
Protocol No.	CS/TAAB/2017/01 Dated: 17/01/2017
Investigator(s):	**Dr. Debashis Deb, MBBS, MS** Consultant, TAAB Biostudy Services, Kolkata **&** **Dr. Arunabha Biswas, MBBS, MD (Pharmacology), DM (Pharmacology)** Asst. Professor, Calcutta National Medical College and Hospital (Govt. of WB), Kolkata
Study Center:	KD Cure Nursing Home, 52 Jodhpur Park, Kolkata -68 and Clinical Unit, TAAB HealthCare Services, Jadavpur, Kolkata-32
Study Period:	**Date first patient was enrolled:** 29/01/2017 **Date last patient was completed:** 21/04/2017
Study Design:	Single centric, open level, single-arm, non-comparative, prospective clinical study to evaluate efficacy and safety of Slimming Tea • Duration: 2 months • Number of subjects: 50
Number of Patients:	**Screened:** 63 **Treated:** 50 **Evaluated for efficacy:** 50 **Evaluated for safety:** 50
Investigational Product (IP):	Slimming Tea manufactured by Tea Experts India Private Limited. Batch No: ST0117 Manufacturing Date: 01/01/2017 Exp. Date: Best before 18 months from manufacture

Inclusion Criteria:	• Male and female subjects in the age group of 21-55 years shall be selected. • Subjects who are having BMI of b/w 25 to more than 30 with no significant history of disease (including anorexia, bulimia or other eating disorders) • Subjects willing to give informed consent. • Subjects willing to perform all study related procedures including the use of study medications, allow the tests and willing to document symptoms and medication • Subjects willing and able to substitute study medication for their pre study prescribed medication for the duration of the study • Subjects {and /or legally accepted representative (LAR)} willing to give written informed consent and ability to adhere to dosing and visit schedules and meet study requirements.
Exclusion Criteria:	• Subjects unlikely to comply with the protocol or unable to understand the nature, scope and possible consequences of the study • Subjects taking prescribed medication; blood pressure ≥ 160/100 mmHg • Subjects currently following a medically prescribed or slimming diet; • Subjects taking part in a human study or giving blood during the previous 4 weeks • Subjects reporting of losing more than 5 kg in past 3 months, dietary irregularity, alcohol abuse, diabetes mellitus, thyroid, kidney or hepatic disease, psychiatric disorders (especially depression, eating disorders, medication) • Inability to carry out testing for the study. • Known Human Immunodeficiency Virus (HIV)-positive status.
Duration of Treatment:	60 days (2 months)
Primary Objectives:	Mean changes of the followings from baseline to end of protocol therapy— • Body weight • BMI and • Waist-hip ration (WHR)
Secondary Objectives:	Mean change in vital signs from baseline to end of protocol therapy.
Safety Objective:	Recording of all Adverse Events (AE's) and Serious Adverse Events
Statistical Methods:	Categorical data between the baseline & post treatment will be compared with the χ^2 test, and continuous data will be compared with ***Student's t-test***

Results:	**Primary Efficacy Evaluations:** Data obtained from the present study, revels that the change of body weight in 60 days after study period was found 1.124 ± 0.794 kg. The weight reduction data found satisfactory. The same has been elaborated in the table-6 and also graphically represented in the figure-1. Figure-3 represents the mean changes in BMI. The slimming tea results in weight reductions. The obtained data clearly indicates that more than average of twelve hundred grams weight has been reduced in 2 months. Therefore, the BMI has been found less than the day of therapy. Because the body mass index (BMI) is a measure which shows whether people have the right weight for their height. If the weight decreases the index may be found less. From the present study the BMI found for day-0 and day-60 are as follows 32.542 ± 2.502 and 32.080 ± 2.532 respectively. Waist–hip ratio or waist-to-hip ratio (WHR) is the ratio of the circumference of the waist to that of the hips. This is calculated as waist measurement divided by hip measurement (W/H). WHR is also helpful in identifying abdominal fat levels. High abdominal fat levels are associated with a high risk for diseases such as hypertension, type II diabetes, and cardiovascular disease etc. Obtained study data indicates that the slim tea is also useful in reducing the WHR. The same has been found 0.977 ± 0.058 for day-0 and 0.980 ± 0.059 for the end of therapy (day-60). The WHR is graphically represented in the figure-3. **Secondary Efficacy Evaluations:** Vital signs (Blood pressure and pulse rate) for the enrolled 50 patients were also evaluated to access the secondary efficacy parameters. The findings are represented in the table-7. It can be concluded form the obtained data that the slimming tea doesn't have any significant effect in vital signs of the patients. The parameters found normal after the treatment period specified in the protocol.
Conclusion	The objective of the present clinical study of Slimming Tea was to evaluate its safety and efficacy in obese and or over Wight patients. A total no of 50 patients were exposed to the product thrice daily for 60 days as mentioned in the study protocol. The obtained data shows that average of 1.124 ± 0.794 kg weight has been reduced after just 2 months treatment. The similar changes were also noticed in the patients for the BMI and WHR. But it may be suggested that the increase in patient population can able to satisfy the significance of the weight reduction after regular consumption of the product (slimming tea). More significant result in weight reduction may be obtained for consumption of the "Slimming Tea" for a period longer than two months. No reported AE of SAE found during the entire study period which concludes that the product is safe.
Date of Report:	24/05/2017

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ABBREVIATIONS USED

CRO	Contract Research Organizations
DCGI	Drugs Controller General of India
CDSCO	Central Drugs standard and Control Organizations
EC	Ethics Committee
ICF	Informed Consent Form
CRF	Case Record Forms
PIS	Patient Information Sheet
IB	Investigators Brochure
AE	Adverse Events
SAE	Serious Adverse Events
LAR	Legally Acceptable Representatives
ICMR	Indian Council of Medical Research
ICH	International Conference on Harmonization
GCP	Good Clinical Practice
CRA	Clinical Research Assistant
IMP	Investigational Medicinal Product
SOP	Standard Operating Procedure
USP	United States Pharmacopoeia
NA	Not Applicable
pK	Pharmacokinetics

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3. ETHICAL CONSIDERATIONS

3.1 Institutional Ethics Committee

The study protocol and all other documents like the subject information sheet, informed consent form (ICF), and investigator's brochure (IB) were submitted to a properly constituted Institutional Ethics Committee (IEC) and approval was received from the IEC before the commencement of the study. Approval from the committee has been documented in a dated letter to the investigator specifying the study title, protocol number (with version number and date) and the details of other documents reviewed. Any amendments to the protocol, other than administrative, were approved by this committee. The Principal Investigator (PI) informed IEC of: Any amendment to the protocol, changes to the ICF, or revisions of other documents originally submitted for review. Any serious adverse events that occurred during the study. Any new information that might have adversely affected the safety of subjects or the conduct of the study.

All correspondence with the IEC was filed by the PI in the investigator's study file, and copies were forwarded to the Contract Research Organization (CRO), TAAB Biostudy Services. **Copies of the protocol and any applicable amendments are provided.**

3.2 Ethical Conduct of the Study

This study was carried out in accordance with the International Conference on Harmonization Good Clinical Practice (ICH GCP), Schedule Y, Indian GCP, Indian Council of Medical Research's (ICMR) Ethical guidelines for biomedical research on human participants, and the principles enunciated in the Declaration of Helsinki [Ethical Principles for Medical Research Involving Human Patients, revised in 59th World Medical Association (WMA) General Assembly, Seoul, October 2008.

3.3 Patient Information and Consent

3.3.1 Informed Consent

The Investigator obtained a signed ICF from each patient prior to his/her participation in the study. Consent was documented by the patient's dated signature. A copy of the signed and dated ICF was provided to the patient prior to his/her participation in the study. Samples of the patient information sheet and the ICF used in this study are presented along with the study protocol provided in clinical study report. The Investigator was responsible for ensuring that facilities and expertise were available to address any medical emergencies during the study. The contact person and address was provided in the ICF to contact in case of emergency.

3.3.2 Patient Data Protection

The investigator ensured that the patients' anonymity was maintained and the confidentiality of records and documents which identified the patients was protected in accordance with applicable regulatory requirements. Patients were identified only by their assigned number and initials on all

case report forms (CRFs), records and documents submitted to the CRO (TAAB Biostudy Services).The investigator however kept a patient identification log with complete identification information (name, address) for each study patient. The investigator maintained documents such as the signed ICF and the patient identification log in strict confidence.

3.3.3 Withdrawal

All patients were free to withdraw from this study at any time and for any reason, specified or unspecified. The investigator was to be informed about any withdrawal immediately.

4. INVESTIGATORS AND STUDY ADMINISTRATIVE TEAM

Principal Investigator:

Dr. Debashis Deb, MBBS, MS
Consultant, TAAB Biostudy Services, Kolkata-32

Co-Investigator:

Dr. Arunava Biswas, MBBS, MD (Pharmacology), DM (Pharmacology)
Asst. Professor, Calcutta National Medical College and Hospital (Govt. of WB), Kolkata

Coordinator:

Prof. (Dr.) T. K. Pal
Technical Advisor, TAAB Biostudy Services, Kolkata-700032

Study Monitoring & Site Management:

Ms. Paulomi Halder, B.Sc., PDGCRRA
Mrs. Manashree Banerjee, BCA
Ms. Minakshi Nath, M Sc., PDGCRRA
Ms. Chandra Nandi, B. Sc, PDGCRRA (pursuing)

Data Management & Statistical Analysis:

Mr. Subhasis Dan, M. Pharm
Mr. Chiranjit Saha, B.Sc

Quality Assurance:

Ms. Easha Biswas, M. Pharm
Dr. Nilendra Chatterjee, M Sc., Ph. D

5. INTRODUCTION

Overweight and Obesity: The terms "overweight" and "obesity" refer to body weight that's greater than what is considered healthy for a certain height. The most useful measure of overweight and obesity is body mass index (BMI).BMI is a person's weight in kilograms divided by the square of height in meters. It is an inexpensive and easy-to-perform method of screening for weight category, for example underweight, normal or healthy weight, overweight, and obesity.

For adults 20 years old and older, BMI is interpreted using standard weight status categories. These categories are the same for men and women of all body types and age. The standard weight status categories associated with BMI ranges for adults are shown in the following table:

BMI	Weight Status
Below 18.5	Underweight
18.5 – 24.9	Normal or Healthy Weight
25.0 – 29.9	Overweight
30.0 and Above	Obese

Green Tea: Preparations of green tea are used as aids in weight loss and weight maintenance. Catechins and caffeine, both contained in green tea, are each believed to have a role in increasing energy metabolism, which may lead to weight loss.

Green tea contains catechins, a class of low molecular weight polyphenols that consist mainly of flavan-3-ol monomers; catechins are present mainly as catechin (C), catechingallate (CG), gallocatechin (GC), gallocatechingallate (GCG), epicatechin (EC), epicatechingallate (ECG), epigallocatechin (EGC), and epigallocatechingallate (EGCG).

Green tea leaves normally contain 10% to 20% catechins, mainly EGCG.EGCG, appear to have antiobesity effects. The consumption of green tea may help reduce body weight, mainly body fat, by increasing postprandial thermogenesis and fat oxidation.

Based on this background information, study rationale, the clinical study will be to perform to evaluate efficacy and safety of Slimming Tea manufactured by the sponsor Tea Experts India Private Limited in reducing the weight, BMI as well as waist-hip ratio (WHR) during two months in overweight and/or obese adults.

6. STUDY OBJECTIVES

6.1 Primary Objectives

To assess the efficacy of the Slimming Tea in reducing the weight during two months study in overweight and/or obese adults.

Primary Endpoint: Primary endpoints includes

- Mean change in body weight from baseline to end of protocol therapy.
- Mean change in BMI from baseline to end of protocol therapy.
- Mean change in Hip-Waist ratio from baseline to end of protocol therapy.

6.2 Secondary Objectives

To assess the safety of the product (Slimming Tea) in overweight or obese adults.

Secondary endpoint includes

- Mean change in vital signs from baseline to end of protocol therapy

6.3 Safety Evaluation

Occurrences of the Adverse Events (AE) and Serious Adverse Events (SAE) during the study period.

7. INVESTIGATIONAL PLAN

7.1 Description of Overall Study Design and Plan

This is a single centric, open label, single-arm, non-comparative and prospective clinical study to evaluate efficacy and safety of Slimming Tea manufactured by the sponsor Tea Experts India Private Limited.

After baseline examination, subjects were informed about the study and were given a handout explaining the study. If they are interested in participating, he/she will be given a consent form to sign. The eligible subjects were enrolled into the study as per the inclusion/ exclusion criteria specified in the study protocol.

75 gm of investigational product will be given to the each subject. Subjects will be advised to take IP thrice a day with breakfast, lunch, and dinner or within 15 minute of the same. Subjects should take approximately 2-2.5 gm of tea mix and brew it with 180 ml (1 cup) of boiling water (not on flame). The tea will be covered with a lid and made to stand for 5-7 minutes. Then it will be strained and consumed without any milk and sugar.

They will be informed to visit the investigator after 60 days Safety monitoring will be done continuously throughout the study.

Safety monitoring was done continuously throughout the study. All adverse events (AEs) were spontaneously reported by the subjects or elicited by the investigators was recorded.

7.2 Selection of Study Population

Patients were included in the study according to the following criteria:

7.2.1. Inclusion Criteria

- Male and female subjects in the age group of 21-55 years shall be selected.
- Subjects who are having BMI of b/w 25 to more than 30 with no significant history of disease (including anorexia, bulimia or other eating disorders).
- Subjects willing to give informed consent.
- Subjects willing to perform all study related procedures including the use of study medications, allow the tests and willing to document symptoms and medication
- Subjects willing and able to substitute study medication for their pre study prescribed medication for the duration of the study
- Subjects {and /or legally accepted representative (LAR)} willing to give written informed consent and ability to adhere to dosing and visit schedules and meet study requirements.

7.2.2 Exclusion Criteria

- Subjects unlikely to comply with the protocol or unable to understand the nature, scope and possible consequences of the study
- Subjects taking prescribed medication; blood pressure $\geq$ 160/100 mmHg
- Subjects currently following a medically prescribed or slimming diet;
- Subjects taking part in a human study or giving blood during the previous 4 weeks
- Subjects reporting of losing more than 5 kg in past 3 months, dietary irregularity, alcohol abuse, diabetes mellitus, thyroid, kidney or hepatic disease, psychiatric disorders (especially depression, eating disorders, medication)
- Inability to carry out testing for the study.
- Known Human Immunodeficiency Virus (HIV)-positive status

7.3 Removal of patients from therapy or assessment

- A withdrawal occurs when the enrolled patient ceases participation in the study, regardless of the circumstances, prior to the completion of the protocol.
- Patients may be withdrawn from the study by the Investigator or Sponsor under the following circumstances
    - ❖ Request by the Patient, who is at any time free to withdraw from the study, without prejudice to further treatment care.
    - ❖ At the discretion of the Investigator.
- Violation of criteria listed in the Protocol
- Noncompliance with Protocol or lost to follow up (in consultation with medical monitor)

- Serious Adverse Event or Reactions on the discretion of the Investigator
- Patients who become pregnant during the study period.

For any patient who withdraws from the study before the study is completed, the investigator will Complete the case report form, indicating the date of withdraw and explanation for the early withdrawal from the study. If possible, provide an overall evaluation of safety of the assigned treatment;

I. Arrange for alternate medical care of the discontinued patient if necessary

II. And record on appropriate case report form pages any follow-up of patients discontinued for adverse experiences.

A withdrawal must be reported immediately to the clinical monitor if it is due to a serious adverse event. The investigator will record the reason for withdrawal from the study, provide or arrange for appropriate follow-up (if required) for such patients, and document the course of the patient's condition.

8. TREATMEANT

8.1 Identification of the Investigational Product (IP)

Table-1: Investigational Product Details

Name	Slimming Tea manufactured by the Tea Experts India Private Limited
Composition	Green Tea (Camellia sinensis), Tulsi (Ocimum sanctum), Rose petal (Rosa), Hibiscus petal (Rosa sinensis), Pepper mint (Menta peprita), Liquorice (Glycyrrhiza uralensis), Cumin (Cuminum cyminum), Senna (Cassia senna), Mint (Mentha), Ginger (Zingiber), Gurmar (Gymnema sylvestre), Aswhagandha (Withania somnifera), Mustard (Brassica), Turmeric (Curcuma longa), Cinnamon (Cinnamamom), Malabar tarmarind (garcinia combogia), Permitted flavours
Batch No.	ST0117
Mfg. Date	01/01/2017
Exp. Date	Best before 18 months from manufacture
Manufactured by	Tifusion (A Unit of Tea Experts India Pvt Ltd), 35 Creek Row, 1st Floor, Kolkata 700 014, India. Customer care No: 033 2226 4440/1 www.teaexpertsindia.com • www.tifusion.in
Storage	Empty contents into an airtight container immediately after opening the seal. Store in a cool dry place.

8.2 Instruction and Doses

75 gm of investigational product will be given to the each subject. Subjects will be advised to take IP thrice a day with breakfast, lunch, and dinner or within 15 minute of the same. Subjects should take

approximately 2-2.5 gm of tea mix and brew it with 180 ml (1 cup) of boiling water (not on flame). The tea will be covered with a lid and made to stand for 5-7 minutes. Then it will be strained and consumed without any milk and sugar.

Table-2: Doses of the Investigational Product (Slimming Tea)

Investigational Product	Clinical Condition	Dose/Dosage Form/Route
Slimming Tea	Overweight and/or obese adults.	Oral/ thrice a day

9. EFFICACY, SAFETY AND PHARMACOKINETIC ASSESSMENTS

The schedule of assessments is shown

Table-3: Study Activity Schedule

Procedures	Initial Visit	Follow up Visit
	Visit 1 (Screening)	Visit 2 (60 days)
Patient's Informed Consent	√	
Inclusion/ Exclusion criteria	√	
Demographic data (Age, Gender, Weight)	√	√
Vital signs	√	√
Date of study drug therapy initiation and prescribed dosage	√	
Study drug	√	
Assessment of patient's compliance with therapy	√	√
Records of adverse drug reaction (related to the study drug)		√
Record of all adverse events		√
Assessment of the patients according to the Primary and Secondary parameters	√	√

9.1 Efficacy Assessments

9.1.1 Measurement of Outcome

The Slimming Tea was evaluated as per the assessment criteria's mentioned in the protocol under heading----**8.1 Efficacy Evaluation** (Primary and Secondary).

9.1.2 Safety parameters

- Incidence of adverse events and serious adverse events during the study period

The Slimming Tea was evaluated as per the assessment criteria's mentioned in the protocol under heading---- **8.2 Safety Evaluation.**

9.1.3 Adverse events:

Mild: Awareness of symptoms but easily tolerated

Moderate: Discomfort enough to cause interference with usual activity

Severe: Incapacitating with inability to work or carry out usual activity

No serious adverse event occurred during the entire duration of the clinical study as well as none of the total 50 patients were withdrawn from the study due to adverse event.

9.1.4 Laboratory safety parameters

Not applicable

9.2 Pharmacokinetic measurements and timing

Not applicable

9.3 Appropriateness of measurements

The efficacy and safety measurements used in this study are generally accepted as reliable and relevant, and were considered appropriate to meet the objectives.

10. DATA QUALITY ASSURANCE

10.1 Data Handling and Record Keeping

Demographic and background information, as well as results relevant to the patient's medical history, physical examination, vital signs and clinical laboratory data were recorded in the appropriate subject CRFs. Case Report Forms were provided by TAAB Biostudy Services. The Investigators were responsible for reporting accurate data on the CRFs. Data reported on the CRF that were derived from source documents were checked for consistency against the source documents. The results of the hematology and biochemistry were recorded together with the normal ranges. Completion of CRFs: Each patient's data was recorded on the appropriate pages of CRF in ink as per the instructions in the CRF. The Investigator was responsible for ensuring that all blank spaces were filled in. If certain data were not available, "NA" was entered in the blank space. Corrections to CRFs: The data entered on original CRFs were corrected in the following way: The entry was struck off (not erased or whitened

out) so as to leave the original entry legible. The correction was entered in black / blue ink, initialed and dated by the authorized person making the change. CRF Flow: Each page of CRF was photocopied. The original was kept by the monitor of the CRO (TAAB Biostudy Services) for the Data Management department. Photo copy remained in the possession of the Investigator. Study management and monitoring representatives of TAAB Biostudy Services conducted site visits to ensure that the study was in line with GCP Guidelines and Regulations, the CRFs were completed correctly, that the protocol was adhered to, to monitor drug accountability and to collect completed pages of the CRF. In order to perform their role, the monitors were given direct access to source documents (original documents, data and records). Direct access included permission to examine, analyze, verify and reproduce any record(s) and report(s) that are important to evaluate the clinical trial. Source documentation was reviewed by representatives from **Tea Experts India Private Limited.** After validating the data, the monitor ensured that the CRFs were forwarded to TAAB Biostudy Services.

10.2 Data management

Clinical data was collected using printed CRFs and electronic file transfer (for lab data). Data was processed at TAAB Biostudy Services. All data was entered into password secured computer system which was operated by single personnel which was to be used for further processing as and when required.

11. STATISTICALMETHODS

11.1 Statistical and analytical plans

Categorical data between the baseline & post treatment will be compared with the χ^2 test, and continuous data will be compared with ***Student's* t-*test***.

11.2 Sample size estimation

In the present study 63 patients was screened, from the screened patient total no of 50 patients was included in the study and treated with the investigational product as specified in the protocol.

11.3 Changes to the analyses made before the blind was broken

This is an open labeled study and no change from the planned analyses was made.

11.4 Changes to the analyses made after the blind was broken

This is an open labeled study and no change from the planned analyses was made.

12. STUDY PATIENTS

Disposition of Patients

In the present study, total 63 patients were screened from which 50 patients were enrolled in the study and treated according to the protocol. 4 patients were screen failed. Total 9 patients were dropped out during the study. Finally 50 patients were evaluated for assessment.

13. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

13.1 Demography

Table-4: Demographic Data of the Enrolled Patients (Screen fail/drop out patients is not included in the list)

Total Patients	Age (year)	Weight (kg)
50	46.7 ± 9.552	78.372 ± 7.244

13.2 Medical history

Patients/Subjects with obesity and or over weight.

14. MEASUREMENT OF TREATMENT COMPLIANCE

All subjects who completed the trial complied with the study treatment which is evident from the investigational medicinal product (IMP) accountability records.

15. PROTOCOL DEVIATIONS

No protocol deviations occurred during the entire duration of the clinical study.

15.1 Deviations relating to selected criteria and resulting in exclusion from the efficacy analyses

No deviations occurred during selection of the subjects

15.2 Randomization and dosing irregularities

No randomization or dosing errors occurred during the study or during the analysis.

16. BREAKING OF THE BLIND

Not applicable as this was an open label trial.

17. DATA SETS ANALYZED

All patients were analyzed for safety and patients other than the withdrawals were analyzed for efficacy. No patient was analyzed for pharmacokinetic parameters.

Baseline Data (Vital signs)

Table-5: Baseline Data (Vital signs) of Patients

No. of Patients	Blood Pressure (mm Hg)		Pulse Rate (/min)
	Systolic	Diastolic	
50	127.26 ± 8.18	80.30 ± 7.04	72.20 ± 4.61

18. EFFICACY EVALUATION

18.1 Primary Efficacy Evaluation

Data obtained from the present study, revels that the change of body weight in 60 days after study period was found 1.124 ± 0.794 kg. The weight reduction data found satisfactory. The same has been elaborated in the table-6 and also graphically represented in the figure-1.

Table-6: Mean Changes in Body Weight (Kg), BMI and Waist-Hip Ratio (WHR)

No. of Patients	Body Weight (Kg)		BMI		WHR	
	Day-1	Day-60	Day-1	Day-60	Day-1	Day-60
50	78.372 ± 7.244	77.248 ± 7.188	32.542 ± 2.502	32.080 ± 2.532	0.977 ± 0.058	0.980 ± 0.059

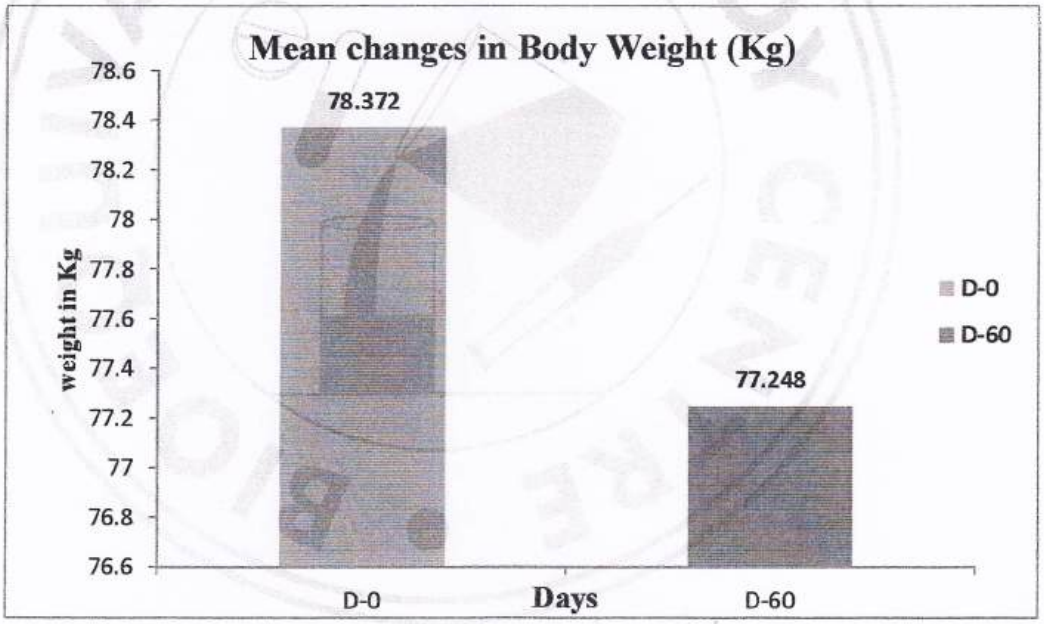

Figure-1: Mean change in body weight from baseline to end of protocol therapy.

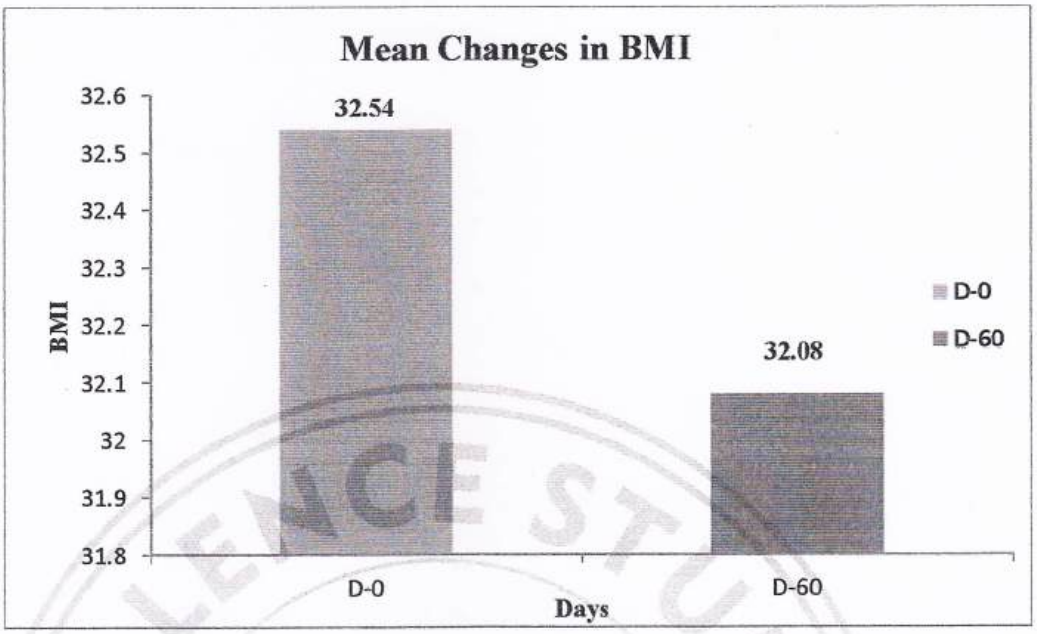

Figure-2: Mean change in BMI from baseline to end of protocol therapy.

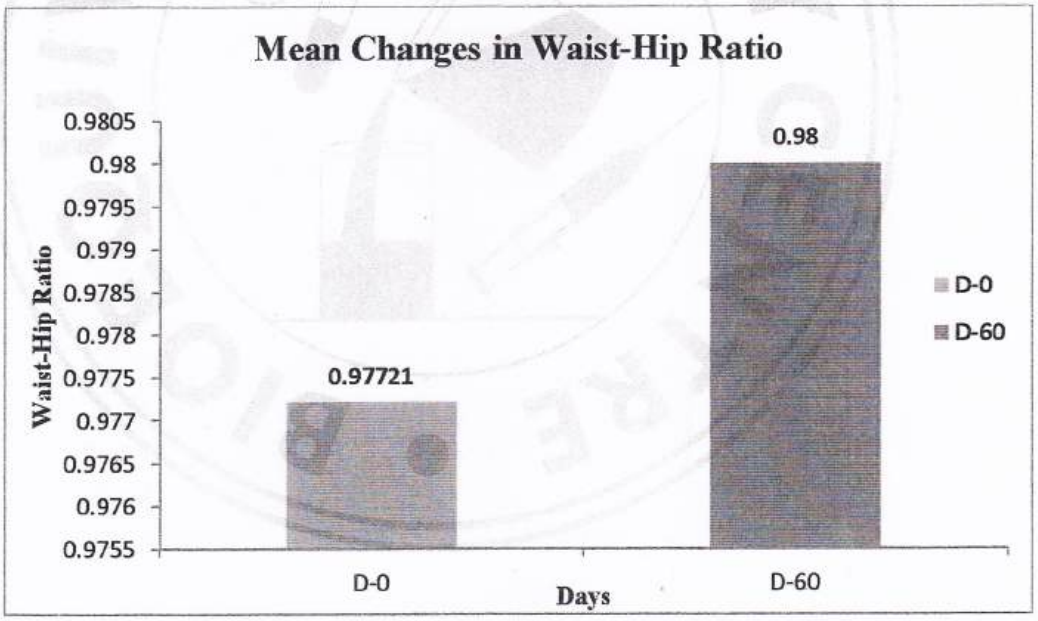

Figure-3: Mean change in Hip-Waist ratio from baseline to end of protocol therapy.

Figure-3 represents the mean changes in BMI. The slimming tea results in weight reductions. The obtained data clearly indicates that more than average of twelve hundred grams weight has been

reduced in 2 months. Therefore, the BMI has been found less than the day of therapy. Because the body mass index (BMI) is a measure which shows whether people have the right weight for their height. If the weight decreases the index may be found less. From the present study the BMI found for day-0 and day-60 are as follows 32.542 ± 2.502 and 32.080 ± 2.532 respectively.

Waist–hip ratio or waist-to-hip ratio (WHR) is the ratio of the circumference of the waist to that of the hips. This is calculated as waist measurement divided by hip measurement (W/H). WHR is also helpful in identifying abdominal fat levels. High abdominal fat levels are associated with a high risk for diseases such as hypertension, type II diabetes, and cardiovascular disease etc. Obtained study data indicates that the slim tea is also useful in reducing the WHR. The same has been found 0.977 ± 0.058 for day-0 and 0.980 ± 0.059 for the end of therapy (day-60). The WHR is graphically represented in the figure-3.

18.2 Secondary Efficacy Evaluations

Vital signs (Blood pressure and pulse rate) for the enrolled 50 patients were also evaluated to access the secondary efficacy parameters. The findings are represented in the table-7.

Table-7: Mean Changes in Vital Signs (Blood Pressure, Pulse)

No. of Patients	Blood Pressure (mmHg)				Pulse (/min)	
	Systolic		Diastolic		Day-1	Day-60
	Day-1	Day-60	Day-1	Day-60		
50	127.26 ± 8.18	126.70 ± 7.02	80.30 ± 7.04	78.22 ± 5.76	72.20 ± 4.61	71.90 ± 4.14

It can be concluded form the obtained data that the slimming tea doesn't have any significant effect in vital signs of the patients. The parameters found normal after the treatment period specified in the protocol.

19. SAFETY EVALUATION

Table-8: Summary Data for Extent of Exposure

Name of the Product	No. of patients exposed	Duration
Slimming Tea	50	60 days

20. ADVERSE EVENTS (AE)

Brief summary of adverse events

An overview of AEs reported in the study is available in table no. 9.

Table-9: Overall Summary of Adverse Events

	Number of patients
All AEs	None
Treatment-emergent AEs	
Treatment-emergent SAEs	
Deaths	
Withdrawals due to AEs	

21. SERIOUS ADVERSE EVENTS (SAE) &SIGNIFICANT ADVERSE EVENTS (AE)

21.1 Deaths

No death occurred during the study.

21.2 Serious adverse events

No serious adverse occurred during the study.

21.3 Treatment-emergent adverse events leading to withdrawal from the study

No patients were withdrawn from the participation in the clinical study due to the adverse event.

21.4 Other significant adverse events

No other significant AEs observed during the study.

22. CLINICAL LABORATORY EVALUATIONS

Not applicable

23. SAFETY CONCLUSIONS

No specific safety concern has emerged from the analysis of the safety data set submitted for the treatment groups.

24. PHARMACOKINETIC EVALUATION

24.1 Plasma concentrations

Not applicable.

24.2 Pharmacokinetic parameters

Not applicable.

24.3 Pharmacokinetic/Pharmacodynamic relationship

Not applicable.

24.4 Pharmacokinetic conclusions

Not applicable.

25. OVERALL CONCLUSIONS

The objective of the present clinical study of Slimming Tea was to evaluate its safety and efficacy in obese and or over Wight patients. A total no of 50 patients were exposed to the product thrice daily for 60 days as mentioned in the study protocol.

The obtained data shows that average of 1.124 ± 0.794 kg weight has been reduced after just 2 months treatment. The similar changes were also noticed in the patients for the BMI and WHR. But it may be suggested that the increase in patient population can able to satisfy the significance of the weight reduction after regular consumption of the product (slimming tea). More significant result in weight reduction may be obtained for consumption of the "Slimming Tea" for a period longer than two months.

No reported AE of SAE found during the entire study period which concludes that the product is safe.

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