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Safety and Efficacy of iSlim Flat Tummies for Weight Management - A Randomised, Double-Blind, Placebo Controlled Clinical Study

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HUMAN

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ABSTRACT

The study's goal was to assess the safety and efficacy of iSlim Flat Tummies for weight management in adult male and/or female obese or overweight subjects. The study included 70 healthy adult male and female subjects who were instructed to take once daily by skipping the lunch. The investigational product, either active or placebo, was given for a period of 3 months (90 days). All were randomized into active and placebo groups (1:1 ratio). The vital sign parameters were found to be normal for all the study subjects and did not have any clinically or statistically significant abnormal values when compared between and within groups, implying that the test product has no safety issues observed after 90 days of oral administration. The measured laboratory parameters were found to be completely normal before and after the treatment periods across all the study groups. There was no protocol deviations observed during the course of the trial. All completed study subjects have 100% compliance with the investigational product. In this study, iSlim Flat Tummies has demonstrated an excellent safety profile when administered orally. Subjects who were in the mild to moderate range of overweight and received iSlim Flat Tummies showed significant improvement in their fasting and postprandial blood glucose levels, or HbA1c values. Leptin, hs-CRP was better than the placebo group arm at the end of the study (Day 90). These results corroborate with various cholesterol parameters (LDL, HDL, VLDL, TC, and TG) and also with the appetite questionnaire, which shows that the mean or average values of appetite improved in the iSlim Flat Tummies receiving group. This study clearly indicates that iSlim Flat Tummies have significant anti-inflammatory (CRP & leptin) effects in the study subjects as well. Therefore, it is concluded that iSlim Flat Tummies has a definite role in improving the overweight condition along with improving the overall appetite when the subjects administered the product orally for 90 consecutive days.

BACKGROUND

Obesity is a condition in which an individual is significantly overweight, and an excessive amount of body fat has accumulated under the chin and on the breasts, belly, buttocks, and/or thighs. Though it is not a serious case in itself, it may shorten the span of life, as well as create diminished efficiency and happiness. Recently, the number of overweight children and adolescents has doubled. Obesity leads to cause a lot of health problems, such as diabetes, gallstones, osteoarthritis, gout, high blood pressure, heart disease, stroke, hypertension, high cholesterol, and some types of cancer. Ayurveda instructs us on how to resist diseases through our food habits and life styles. In Ayurveda, atisthaulya (obesity) is regarded as medoroga, a disorder of the medadhatu, which includes fat tissue and fat metabolism. Obesity begins with an imbalance of the doshas (Vata, Pita, and Kapha), an imbalance of agni (digestive fire), an imbalance of the malas (waste products) or an imbalance of the shrotas (microcirculatory channels). This collection of imbalances then interferes with the formation of tissues, or dhatus, and leads to a tissue imbalance that we experience as excess weight. The treatments given to obese people include increased physical activity and reduced calorie intake. When the behavioral approach is not sufficient, a pharmacologic treatment is recommended. The treatment given for obesity leads to adverse effects, and the numerous drugs used have been withdrawn from the market. Some drugs can cause weight gain, such as antidepressants, steroids, and diabetes medications, for example. An individual's behavior, socioeconomic status, culture, and environmental factors also contribute to overweight and obesity. In addition, hormones in the brain, the gastrointestinal tract, and in fat cells themselves influence his or her metabolism, eating habits and ultimately weight gain.

iSlim Flat Tummies is a bar formulation with a variety of natural herbal ingredients in a synergistic blend that has been shown to combat cravings and boost fat burning and weight management. iSlim Flat Tummies is a proprietary bar formula designed effectively with powerful botanicals like *Salacia reticulata, Coleus forskohlii* and *Sesamum indicum*. It also contains vitamins and minerals. This herbal supplement offers a comprehensive weight-management support. This can help you to achieve a healthy weight, and has no negative side effects. iSlim Flat Tummies results in giving more stamina, a better-functioning body and more youthful appearance. It contains time tested herbal extracts and naturally derived plant proteins that improve immune function, boosts metabolism in body, act as appetite suppressant, fat blocker, hepatoprotective and supports healthy weight loss while it

effectively flattens your tummies. iSlim Flat Tummies is a best weight management bar, enchanting with mouth-watering taste.

STUDY OBJECTIVES

1. The primary objective was to evaluate the safety of iSlim Flat Tummies in male or female obese or overweight subjects from baseline to the end of the trial.
2. The secondary objective was to evaluate the efficacy of iSlim Flat Tummies in body weight management in male or female obese or overweight subjects from baseline to the end of the trial.

STUDY DESIGN

Design: A randomized, multi-center, double-blind, parallel assignment, placebo-controlled, two arm study.

Study Treatment Allocation: All 70 subjects (healthy adult male and female subjects) were randomized into active and placebo groups (1:1 ratio) and given the following treatment:

GroupI-iS

GroupII-Pb

Randomization (assignment to treatment sequence): Investigational products (IP) duly labeled with randomization codes were provided to the investigators by the sponsor through Radiant Research. As per the randomization schedule the investigator then dispensed IP sachets, two for each subject/day. The IPs was kept by the investigator in a safe but accessible place.

Overall Study Plan: After obtaining the Ethics committee's approval, subjects were asked to visit the site. Informed consent was administered to study volunteers, and after obtaining their consent in writing, the subjects were asked about their medical histories and the investigator conducted a physical examination. Demographics and vital signs were recorded. Blood sample was drawn from each subject for analysis of hematology, biochemistry and virology. Subjects were enrolled in the study after all the Inclusion criteria (IC) and Exclusion criteria (EC) were met. Once the subject was found to be eligible, he or she was allowed to visit the site as baseline visit (Day 1), where the IPs was dispensed sufficiently until the next scheduled visit. Blood samples were collected during Visit 2 and 3 (Day 45 and 90

respectively) for serum insulin and biomarkers (ESR, hsCRP, leptin, and ediponectin), CBC/haematology, Renal Function Test (RFT) and Liver Function Test (LFT) on screening day and day 90 only. The Short Nutritional Assessment questionnaire (SNAQ) was filled on screening visit, visit II, and the last visit.

Inclusion Criteria

Subjects fulfilling following criteria were included in the study:

1. Adult males and non-pregnant females aged 18 to 55 years
2. BMI ≥ 25 kg/m2 to 40 kg/m2 with one or more of the metabolic risk factors (waist circumference ≥80 cm, fasting glucose ≥100 mg/dL, BP ≥130/85 mmHg, HDL-cholesterol <50 mg/dL or controlled diabetes, hypertension, or dyslipidemia with medications).
3. Able to comply with all required study procedures and schedule.
4. Able to comply and willing to follow the prescribed diet plan.
5. Willing and able to give written, informed consent.
6. Subjects who agree to stop using supplements during the study duration.
7. Subjects willing to refrain from any obesity treatment
8. Subjects willing to follow the suggested diet plan

Exclusion criteria

Subjects fulfilling any one of the following criteria were excluded from the study:

1. Participants with uncontrolled hypertension (systolic blood pressure (SBP) >180 mmHg, or diastolic blood pressure (DBP) >120 mmHg)
2. Participants with hepatic disease (aspartate aminotransferase (AST)/alanine amino transferase (ALT) >3 x institutional upper limit of normal) or renal disease (serum creatinine >2.0 mg/dL)
3. Participants with significant cardiovascular disease or stroke
4. Participants with a history of seizures
5. Endocrine diseases such as hypothyroidism or Cushing syndrome
6. History or existence of neurological or psychological disease (schizophrenia, epilepsy, alcoholism, drug addiction, anorexia, bulimia, and so on)
7. Use of medication within the past 3 months that could have an effect on weight (appetite suppressant, laxative, oral steroid, thyroid hormone, amphetamine, cyproheptadine, phenothiazine, or medication having an effect on absorption, metabolism, and excretion).

8. A know history or present condition of allergic response to any pharmaceutical products or supplements.
9. History of weight reduction surgery, bariatric surgery and so on
10. Weight loss more than 10%in the past 6 months
11. Women in childbearing age unable to practice any form of contraception
12. Participants who use herbal supplements or any other wellness product.
13. History of alcohol, tobacco, substance or drug abuse
14. Subject who has participated in a clinical study within the last 30 days before enrolling in this study.
15. Participants with hypersensitivity to any of the ingredients of the study products.
16. Refusing consent or a physician uncomfortable with patient compliance to treatments or follow up.

TREATMENT OF SUBJECTS

Treatment: iSlim Flat Tummies is a bar formulation with many kinds of natural herbal ingredients that are ingested once daily by skipping lunch. The investigational product, either active or placebo, was given for a period of 3 months (90 days).

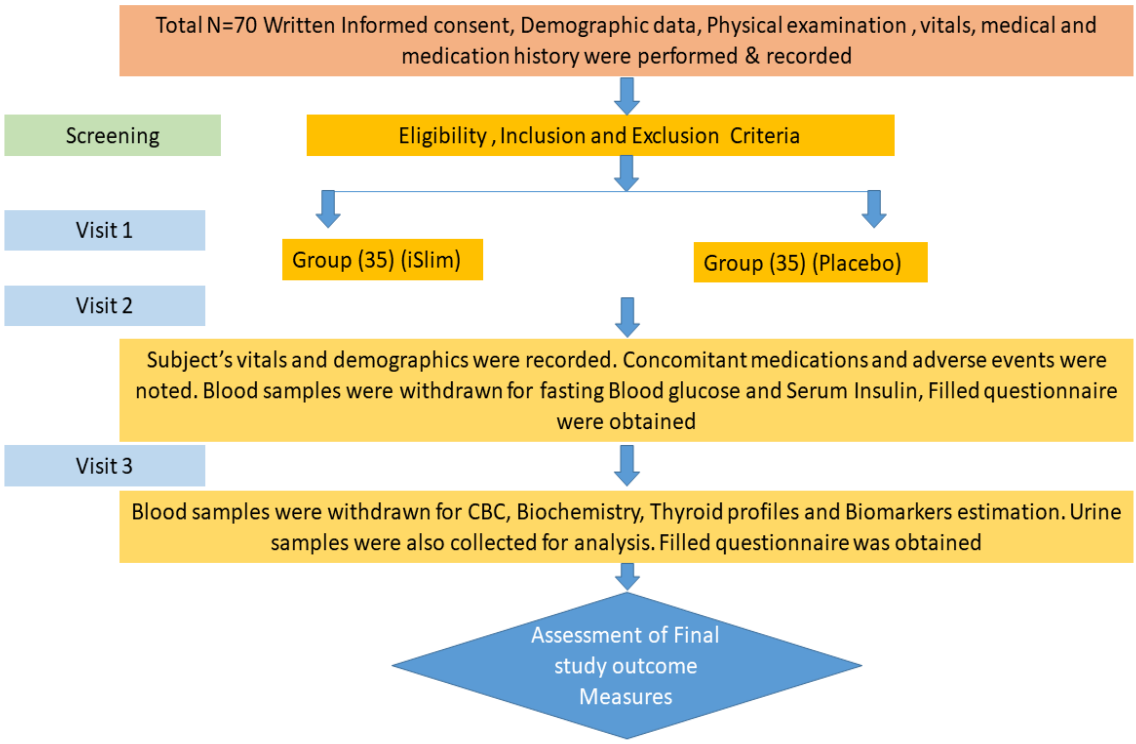
Randomization: Investigational products, duly labelled, were provided to the investigators by the sponsor through Radiant Research. Randomization codes were generated. The IPs were kept by the investigator in a safe but accessible place.

INVESTIGATIONAL PRODUCT

Study Product Description

Products	iSlim, Placebo
Dosage Form	Bar
Generic Name	NA
Marketed By	Indus Viva Health Sciences Pvt. Ltd

Flow Chart of Study Activities



ASSESSMENT OF SAFETY

Specification of Safety Parameters

The current study's safety parameters included vital signs and adverse events, which were compared from the subjects' baseline to the final visit.

Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

Adverse Events (AE)

AE, if any, were reported as per the guidelines of ICH E6. Any medical condition that was present at the time that the subject was screened were considered as baseline and not reported as an AE. However, if it deteriorated at any time during the study, it was recorded as an AE. All AEs were graded for severity (mild, moderate, severe and life threatening) and relationship to the study product (associated or not associated).

Any other important medical event that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse experience (SAE) when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above. All SAEs were recorded

on the appropriate CRF and SAE form, followed through with resolution by a study clinician reviewed and evaluated by a study clinician.

Reporting Procedures

For Adverse Events (AEs)

- Through telephone contacts and subject visits to the study site, the investigator and/or designee inquired about adverse experiences and documented the inquiry in the subject's medical chart.
- During visits to the site, the monitor ensured that if an adverse experience was found, the study coordinator documented the following in the subject's chart and Case Report Form:
- Date and time (if applicable) the event started and ended.
- Description of the event
- Severity of the event
- Outcome of the event
- Action taken and
- Relationship to the study supplement

For Serious Adverse Events (AEs)

Any AE considered serious by the PI or Sub investigator or which meets the afore mentioned criteria was supposed to be submitted on an SAE form to Sponsor INDUS VIVA HEALTH SCIENCES PVT. LTD, Nandi Durga Rd, Jayamahal Extension, Benson Town, Bengaluru, Karnataka 560046.

Follow–up of Subjects after Adverse Events

The investigator took all appropriate necessary precautions to ensure the subject's safety; in particular he was prepared to monitor the outcome of any adverse events (clinical signs, or other) until the subject's condition return to normal or consolidation of the subject's condition (stabilized).

Investigational Product accountability and compliance

1. The investigator, pharmacist, or other authorized individual (i.e., as indicated on the Study Responsibilities Form) dispensed the study supplement to subjects who met the eligibility criteria in accordance with the protocol.

2. The pharmacist, study coordinator, or other authorized individual ensured that each subject had a unique subject identification number.

3. The pharmacist or study coordinator had maintained a record of IP dispensed to each subject. To accomplish this, the pharmacist or study coordinator used the CRF, Study Subject Investigational Product Dispensing Record.

4. The appropriate data was entered into the CRF, if appropriate. The study coordinator or pharmacist kept the IP accountability in the CRF pages updated, regardless of when the monitor performs final accountability.

5. All the unused investigational products were then returned to sponsor at the end of the trial.

RESULTS

The IP codes for the 2 groups were unblinded towards the end of the study during statistical analysis and it was revealed that Group I (Treatment A) received iSlim Flat Tummies, Group II (Treatment B) received placebo products, respectively.

Demographics and baseline characteristics

Table 1 A: Descriptive statistics–Demographics: Age and Sex

Parameter/Statistics	Treatment A	Treatment B
Age (Years)		
N	35	35
Mean(SD)	39.1 (7.81)	41.1 (8.05)
Median	39.0	41.0
Min, Max	23, 54	26, 55
Sex, n (%)		
Female	16 (45.7)	11 (31.4)
Male	19 (54.3)	24 (68.6)

Table 1 B: Descriptive statistics–Demographics (Height, Weight, BMI, Waist Circumference)

Parameter/ Statistics	Visit	Height (in Centimeters)		Weight (in Kilograms)		BMI (inkg/m2)		Waist Circumference	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Screening	35	35	35	35	35	35	35	35
Mean(SD)	Screening	165.8 (8.99)	166.7 (6.68)	84.3 (5.72)	84.7 (6.30)	30.746 (2.3248)	30.494 (2.1267)	110.7 (7.29)	112.3 (7.30)
Median	Screening	165.0	168.0	82.0	85.0	30.119	30.346	109.0	112.0
Min,Max	Screening	150,180	152,180	76,98	69,95	27.16,34.80	27.38,34.81	99,129	101,130
N	Visit 2	35	35	35	35	35	35	35	35
Mean(SD)	Visit 2	165.8 (8.99)	166.7 (6.68)	81.1 (5.58)	80.3 (6.03)	29.609 (2.2855)	28.939 (2.2090)	105.3 (11.68)	105.4 (12.21)
Median	Visit 2	165.0	168.0	80.0	81.0	29.385	28.408	101.0	104.0
Min,Max	Visit 2	150,180	152,180	72,96	65,90s	25.00, 33.78	25.65,33.60	91,130	89,129
N	Visit 3	35	35	35	35	35	35	35	35
Mean(SD)	Visit 3	165.8 (8.99)	166.7 (6.68)	78.7 (5.38)	76.0 (6.70)	28.705 (2.2516)	27.397 (2.5801)	99.4 (12.62)	99.2 (14.22)
Median	Visit 3	165.0	168.0	77.0	76.	28.300	26.854	94.0	95.0
Min,Max	Visit 3	150,180	152,180	70,92	62,87	24.07,33.20	23.51,32.80	85,125	83,127

Safety Results:

Table 2 A: Descriptive statistics for vital signs

Parameter/ Statistics	Visit	Temperature (Fahrenheit)		Heart rate(beats/min)		Pulse rate(beats/min		Respiratory rate (breaths /min)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Screening	35	35	35	35	35	35	35	35
Mean (SD)	Screening	98.12 (0.512)	97.99 (0.405)	76.9 (6.00)	77.5 (5.56)	76.9 (6.00)	77.5 (5.56)	17.7 (1.45)	17.5 (1.38)
Median	Screening	98.2	98	76	78	76	78	18	17
Min, Max	Screening	96.4,99.0	97.2,98.7	64,87	64,89	64,87	64,89	15,21	16,20
N	Visit 1	35	35	35	35	35	35	35	35
Mean (SD)	Visit 1	98.15 (0.419)	98.17 (0.288)	78.1 (6.95)	79.5 (6.30)	78.1 (6.95)	79.5 (6.30)	17.8 (1.65)	17.7 (1.60)
Median	Visit 1	98.2	98.2	78	79	78	79	17	18
Min, Max	Visit 1	97.5,98.9	97.4,98.7	64,89	64,89	64,89	64,89	16,22	15,22
N	Visit 2	35	35	35	35	35	35	35	35
Mean (SD)	Visit 2	98.09 (0.460)	98.10 (0.441)	76.9 (5.46)	77.7 (5.32)	76.9 (5.46)	77.7 (5.40)	17.5 (1.17)	17.3 (1.28)
Median	Visit 2	98.2	98.1	79	78	79	78	17	17
Min, Max	Visit 2	96.9,98.9	97.3,98.9	64,86	64,89	64,86	64,89	16,20	15,20
N	Visit 3	35	35	35	35	35	35	35	35
Mean(SD)	Visit 3	97.42 (1.503)	97.61 (1.337)	73.9 (6.65)	77.8 (6.86)	74.0 (6.68)	77.8 (6.84)	16.9 (1.53)	16.6 (1.57)
Median	Visit 3	98.2	98.4	75	79	75	79	17	16
Min, Max	Visit 3	94.5, 99.0	94.5, 99.2	61, 86	62, 89	61, 86	62, 89	14, 20	14, 20

Table 2 B: Descriptive statistics for vital signs- Systolic and Diastolic Blood Pressure (mmHg)

Parameter/ Statistics	Visit	Systolic Blood Pressure(mmHg)		Diastolic Blood Pressure(mmHg)	
		Treatment A	Treatment B	Treatment A	Treatment B
N	Screening	35	35	35	35
Mean(SD)	Screening	127.2(4.82)	128.0(4.13)	83.9(3.73)	84.1(3.64)
Median	Screening	126	127	84	84
Min,Max	Screening	120,137	118,137	78,92	77,92
N	Visit 1	35	35	35	35
Mean(SD)	Visit 1	126.6(4.39)	127.9(3.71)	84.2(3.85)	84.8(3.86)
Median	Visit 1	127	128	84	85
Min,Max	Visit 1	120,136	119,136	78,92	77,92
N	Visit 2	35	35	35	35
Mean(SD)	Visit 2	126.4(3.87)	125.3(4.29)	80.3(4.54)	81.3(5.11)
Median	Visit 2	126	126	80	82
Min,Max	Visit 2	116,134	116,134	72,92	71,92
N	Visit 3	35	35	35	35
Mean(SD)	Visit 3	120.3(7.24)	121.5(9.64)	75.5(9.54)	75.4(10.04)
Median	Visit 3	120	122	80	79
Min,Max	Visit 3	110,134	100,140	60,92	60,92

Table 3 A: Descriptive statistics for Lab Data

Parameter/ Statistics	Visit	Hemoglobin (gm/dl)		Red Blood Cells (cells/mm3)		Total Leukocyte Count (cells/cumm)		Platelet Count (Lakhs)		ESR (mm1sthr)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Screening	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Screening	14.02 (1.727)	13.82 (1.896)	4.33 (0.777)	4.57 (0.732)	3.09 (0.759)	3.33 (0.808)	3.09 (0.759)	3.33 (0.808)	12.0 (6.66)	12.3 (5.90)
Median	Screening	13.5	14	4.2	4.7	3.1	3.1	3.1	3.1	8	11
Min,Max	Screening	11.7, 18.0	10.7, 18.0	3.0,5.9	3.1,5.9	1.7,4.9	1.9,5.2	1.7,4.9	1.9,5.2	4,29	5,28
N	Visit 3	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Visit 3	14.58 (1.646)	14.59 (1.687)	4.03 (0.804)	4.34 (0.763)	3.31 (0.813)	3.49 (0.771)	3.31 (0.813)	3.49 (0.771)	8.4 (4.02)	8.1 (4.02)
Median	Visit 3	14.1	14.7	3.9	4.2	3.5	3.6	3.5	3.6	6	7
Min,Max	Visit 3	11.9,18.5	11.3,19.0	3.0,5.6	3.0,5.6	1.6,4.7	1.9,4.7	1.6,4.7	1.9,4.7	5,18	5,21

Table 3 B: Descriptive statistics for Lab Data

Parameter/ Statistics	Visit	Neutrophils (%)		Lymphocytes (%)		Monocytes (%)		Basophils (%)		Eosinophils (%)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Screening	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Screening	63.3 (2.11)	63.8 (2.57)	27.1 (2.88)	26.3 (2.35)	5.7 (2.08)	6.1 (2.38)	0.9 (0.59)	0.8 (0.53)	3.8 (1.65)	3.5(1.44)
Median	Screening	63	65	27	27	6	6	1	1	4	3
Min,Max	Screening	60,70	59,69	20,34	20,32	1,9	0,12	0,3	0,3	0,6	0,6
N	Visit 3	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Visit 3	62.9 (2.62)	62.6 (2.12)	28.3 (3.06)	28.1 (2.66)	5.0 (2.61)	5.3 (2.19)	0.6 (0.40)	0.7 (0.43)	3.8 (2.22)	3.6(1.93)
Median	Visit 3	63	63	29	29	5	5	0.6	0.7	4	3
Min,Max	Visit 3	55,69	58,67	20,33	22,35	0,10	0,9	0,1	0,2	0,10	0,8

Table 3 C: Descriptive statistics for Lab Data

Parameter/ Statistics	Visit	SGOT (IU/L)		SGPT (IU/L)		Bilirubin (Total) (mg/dl)		Urea (mg/dl)		Serum Creatinine (mg/dl)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Screening	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Screening	42.6 (5.99)	42.4 (6.92)	41.8 (7.18)	43.2 (5.92)	0.85 (0.412)	0.76 (0.334)	36.9 (7.45)	38.0 (8.18)	1.037 (0.2857)	1.131(0.2 992)
Median	Screening	43	41	42	43	0.8	0.7	38	38	1.02	1.12
Min,Max	Screening	30,55	30,56	22,59	32,58	0.3,1.9	0.3,1.8	17,51	16,58	0.52,1.69	0.69,1.74
N	Visit 3	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Visit 3	37.8 (5.68)	34.7 (6.77)	38.3 (7.42)	35.9 (6.61)	0.60 (0.192)	0.58 (0.200)	29.4 (7.57)	27.7 (5.97)	0.897 (0.2453)	0.973 (0.2607)
Median	Visit 3	37	34	39	37	0.6	0.6	29	27	0.87	0.96
Min,Max	Visit 3	25,51	22,50	25,54	22,52	0.2,0.9	0.2,0.9	14,48	13,42	0.51,1.51	0.46,1.45

Table 3 D: Descriptive statistics for Lab Data

Parameter/ Statistics	Visit	Fasting Blood Glucose (mg/dl)		Serum Insulin (pmol/L)		HbA1C (%)	
		Treatment A	Treatment B	Treatment A	Treatment B	Treatment A	Treatment B
N	Screening	35	35	35	35	35	35
Mean(SD)	Screening	106.1(14.01)	104.9(10.34)	144.1(18.89)	151.1(14.94)	5.21(0.734)	5.22(0.727)
Median	Screening	106	107	150	152	5.1	5.2
Min,Max	Screening	71,132	78,124	104,170	119,174	3.8,6.9	4.0,6.9
N	Visit 3	35	35	35	35	35	35
Mean(SD)	Visit 3	7.0(7.61)	96.3(7.55)	137.7(18.22)	136.9(16.58)	4.81(0.531)	4.75(0.509)
Median	Visit 3	98	97	139	140	4.7	4.7
Min,Max	Visit 3	79,110	72,108	99,171	103,164	4.0,6.0	3.8,6.0

Table 3 E: Descriptive statistics for Lab Data

Parameter/ Statistics	Visit	T3 (ng/dl)		T4 (ng/dl)		TSH (ng/dl)	
		Treatment A	Treatment B	Treatment A	Treatment B	Treat-ment A	Treat-ment B
N	Screening	35	35	35	35	35	35
Mean(SD)	Screening	124.1(23.19)	128.4(25.45)	2.0(0.48)	1.9(0.45)	2.0(1.26)	1.8(1.20)
Median	Screening	120	131	2	1.9	1.8	1.8
Min,Max	Screening	89,162	85,173	1,3	1,3	0,4	0,4
N	Visit 3	35	35	35	35	35	35
Mean(SD)	Visit 3	120.0(31.04)	118.6(27.58)	1.7(0.58)	1.6(0.36)	1.8(1.12)	1.4(0.91)
Median	Visit 3	112	116	1.6	1.6	1.5	1.1
Min,Max	Visit 3	78,186	79,191	1,3	1,2	0,4	0,4

Table 3 F: Descriptive statistics for Lab Data

Parameter/ Statistics	Visit	LDL (mg/dl)		HDL (mg/dl)		VLDL (mg/dl)		Triglycerides (mg/dl)		Total Cholesterol-TC (mg/dl)	
		Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B	Treat-ment A	Treat-ment B
N	Screening	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Screening	172.7 (27.30)	173.9 (31.05)	47.1 (8.71)	47.3 (9.76)	33.9 (7.46)	35.2 (6.28)	187.8 (41.59)	192.1(48.50)	243.6(27.99)	242.6(31.47)
Median	Screening	163	160	46	49	31	35	200	192	231	234
Min,Max	Screening	145,240	139,263	27,65	23,70	21,57	25,48	131,256	131,280	210,300	164,291
N	Visit 3	35	35	35	35	35	35	35	35	35	35
Mean(SD)	Visit 3	136.0 (11.62)	133.1 (13.97)	46.6 (14.09)	43.7 (12.00)	23.3 (3.38)	24.7 (5.46)	135.8 (18.49)	135.1 (11.31)	198.7 (18.72)	187.7(24.18)
Median	Visit 3	138	134	43	41	23	24	135	134	198	192
Min,Max	Visit 3	102,158	102,172	20,91	18,70	16,29	14,38	101,212	119,169	141,236	104,220

Table 3 G: Descriptive statistics for Lab Data

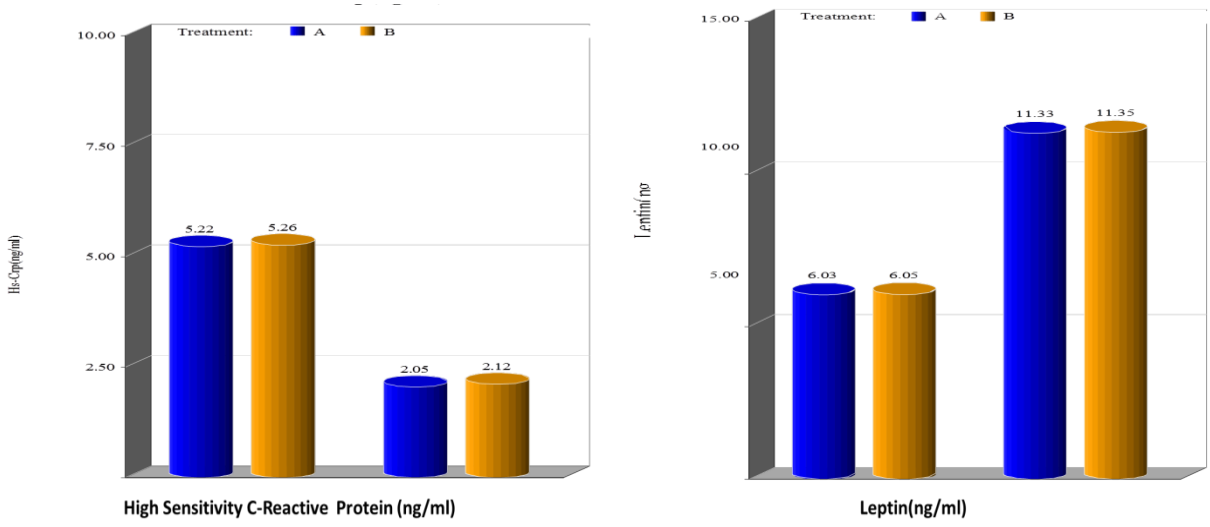
Parameter/ Statistics	Visit	Specific Gravity (1.005-1.020)		pH(5.0-8.0)	
		Treatment A	Treatment B	Treatment A	Treatment B
N	Screening	35	35	35	35
Mean(SD)	Screening	1.012(0.0046)	1.012(0.0047)	6.39(0.829)	6.32(0.869)
Median	Screening	1.012	1.013	6.3	6.3
Min,Max	Screening	1.01,1.02	1.00,1.02	4.8,7.9	4.6,8.0
N	Visit 3	35	35	35	35
Mean(SD)	Visit 3	1.013(0.0041)	1.012(0.0037)	6.65(0.640)	6.65(0.809)
Median	Visit 3	1.013	1.012	6.6	6.8
Min,Max	Visit 3	1.01,1.02	1.01,1.02	5.3,7.8	4.0,8.0

ASSESSMENT OF EFFICACY

Efficacy variable(s)

Table 4: Comparative Descriptive Statistics for Efficacy parameters-High Sensitivity C - reactive protein (ng/ml) and Leptin (ng/ml)

Parameter/ Statistics	Visit	High Sensitivity C - reactive protein (ng/ml)		Leptin(ng/ml)	
		Treatment A	Treatment B	Treatment A	Treatment B
N	Screening	35	35	35	35
Mean (SD)	Screening	5.224 (2.4966)	5.261 (2.5258)	6.033 (3.9689)	6.047 (3.9135)
Median	Screening	6.33	6.54	2.954	3.281
Min, Max	Screening	2.13, 8.32	2.01, 8.32	2.03, 11.62	1.97, 11.81
N	Visit 3	35	35	35	35
Mean(SD)	Visit 3	2.048(0.2358)	2.115(0.2839)	11.325(0.8506)	11.353(0.9822)
Median	Visit 3	2.02	2.11	11.21	11.36
Min, Max	Visit 3	1.64,2.84	1.69,2.97	9.47,13.10	9.65,13.01



Graph 1: Comparative Descriptive Statistics for Efficacy parameters High Sensitivity C - reactive protein (ng/ml) and Leptin(ng/ml)

p- value for Efficacy Parameters–

	Visit	Treatment Difference	Estimate	Standard Error	tValue	p-value	Significant
High Sensitivity C-Reactive Protein (ng/ml)	Visit_3	Avs.B	-0.06508782	0.04920678	-1.32	0.1904	
Leptin(ng/ml)	Visit_3	Avs.B	-0.02718120	0.21451709	-0.13	0.8996	No

Table 5: Descriptive Statistics for Efficacy Parameter–My appetite is

Parameter/Statistics	Visit	Treatment A	Treatment B
My appetite is			
Very poor	Screening	0(0.0)	0(0.0)
poor	Screening	0(0.0)	0(0.0)
average	Screening	10(28.6)	4(11.4)
good	Screening	15(42.9)	18(51.4)
Very good	Screening	10(28.6)	13(37.1)
Very poor	Visit 3	2(5.7)	0(0.0)
poor	Visit 3	9(25.7)	7(20.0)
average	Visit 3	7(20.0)	8(22.9)
good	Visit 3	7(20.0)	10(28.6)
Very good	Visit 3	10(28.6)	10(28.6)

Table 6: Descriptive Statistics for Efficacy Parameter-When I eat

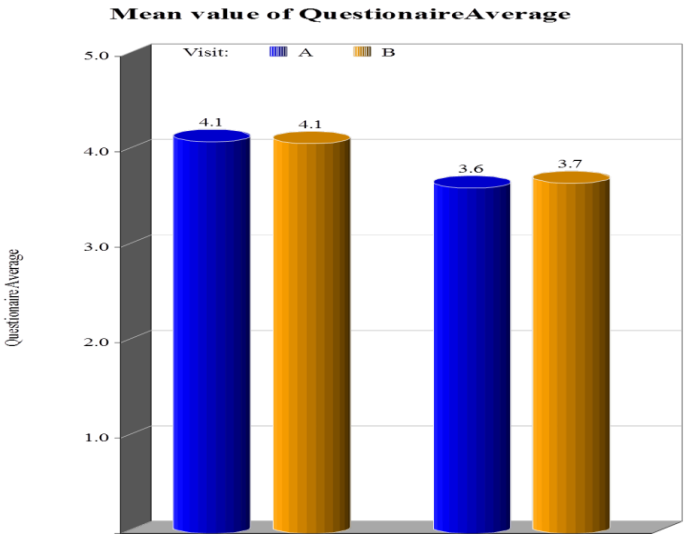
Parameter/Statistics	Visit	Treatment A	Treatment B
When I eat			
I feel full after eating only a few mouthfuls	Screening	0(0.0)	0(0.0)
I feel full after eating about a third of a meal	Screening	1(2.9)	0(0.0)
I feel full after eating over half a meal	Screening	11(31.4)	7(20.0)
I feel full after eating most of the meal	Screening	16(45.7)	21(60.0)
I hardly ever feel full	Screening	7(20.0)	7(20.0)
I feel full after eating only a few mouthfuls	Visit 3	0(0.0)	0(0.0)
I feel full after eating about a third of a meal	Visit 3	2(5.7)	1(2.9)
I feel full after eating over half a meal	Visit 3	10(28.6)	10(28.6)
I feel full after eating most of the meal	Visit 3	16(45.7)	19(54.3)
I hardly ever feel full	Visit 3	7(20.0)	5(14.3)

Table 7: Descriptive Statistics for Efficacy Parameter–Food tastes

Parameter/Statistics	Visit	Treatment A	Treatment B
Food tastes			
Very bad	Screening	0(0.0)	0(0.0)
bad	Screening	0(0.0)	0(0.0)
average	Screening	0(0.0)	2(5.7)
good	Screening	13(37.1)	19(54.3)
Very good	Screening	22(62.9)	14(40.0)
Very bad	Visit 3	0(0.0)	0(0.0)
bad	Visit 3	2(5.7)	7(20.0)
average	Visit 3	12(34.3)	7(20.0)
good	Visit 3	12(34.3)	11(31.4)
Very good	Visit 3	9(25.7)	10(28.6)

Table 8: Descriptive Statistics for Efficacy Parameter–Normally I eat

Parameter/Statistics	Visit	Treatment A	Treatment B
Normally I eat			
Less than one meal a day	Screening	0(0.0)	0(0.0)
One meal a day	Screening	0(0.0)	2(5.7)
Two meals a day	Screening	7(20.0)	12(34.3)
Three meals a day	Screening	22(62.9)	14(40.0)
More than three meals a day	Screening	6(17.1)	7(20.0)
Less than one meal a day	Visit 3	0(0.0)	1(2.9)
One meal a day	Visit 3	9(25.7)	5(14.3)
Two meals a day	Visit 3	7(20.0)	11(31.4)
Three meals a day	Visit 3	12(34.3)	10(28.6)
More than three meals a day	Visit 3	7(20.0)	8(22.9)



Graph 2: Mean Value of Questionnaire Scores

Table 9: p-value for Efficacy Parameters–Questionnaire

Visit	Treatment Difference	Estimate	Standard Error	T Value	p-value	Significant
Visit 3	Avs. B	-.07808826	0.12633758	-0.62	0.5386	No

Statistical Analysis

The data generated from individual CRFs were compared between groups from Day 0 until Day.

90. A student t test was employed for analyzing efficacy values between different visits, while 'p' value <0.05 was considered as statistical significance for the study.

DISCUSSION

iSlim Flat Tummies is a proprietary formula designed for effective weight management. It is enriched with time tested herbal extracts, powders, and naturally derived proteins that provide the food and energy required for daily life.

The trial was conducted in Government General Hospital (Old RIMSGGH), Srikakulam – 532001, Andhra Pradesh, India and Medstar Hospital 614, 171/3, Kodigehalli Main Rd, opp. Chairman's Club, Shanthivana, Sanjeevini Nagar, Bengaluru, Karnataka 560092 India, post Institutional Ethics Committee approval /favorable opinion on the trial proposal.

Eligible subjects were enrolled into the study only after obtaining their consent in writing. The first patient's first visit was on24 Feb 2021, last patient's first visit was on 01 Oct 2021 and last patient's last visit was on 30 Dec 2021. Subjects of the same age group, height, weight, BMI, and other demographics (Table 1) between the 2 treatment arms with the majority being male were enrolled.

Safety Parameters: Vital signs for the 2 treatment group subjects were measured at all the study visits. Table 2 shows the average temperature of study subjects across all the visits. Similarly, other vital parameters include heart rate (Table 3), pulse rate (Table 4), respiratory rate (Table 5), systolic blood pressure (Table 6) and diastolic blood pressure (Table 6). These vital sign parameters were found to be normal for all the study subjects and did not have any clinical or statistically significant abnormal values when compared between and within groups, implying that the test product has no safety issues post 90 days of oral administration.

Physical examination and medical history (Table 7), were completely normal across all the treatment groups across all the study visits. None of these safety lab data point have any statistically significant changes from their baseline (Day 0) visit values to their respective last (Day 90) visit values. This indicates that the product under testing is completely safe for oral consumption.

Laboratory safety Data: The measured hematology parameters like hemoglobin, RBC, WBC, platelet count, ESR, neutrophils, lymphocytes, monocytes, basophils, eosinophils & serum chemistry parameters like SGOT, SGPT, total bilirubin, blood urea, serum creatinine were found to be completely normal before and after the treatment periods across all the study groups.

Efficacy parameters: Glycemic control, thyroid and obesity related parameters were assessed through HbA1c, fasting blood glucose, serum insulin. T3, T4, TSH, LDL, HDL, VLDL, TG, TC considered as a gold standard. Multiple clinical studies confirmed that mean HbA1c level was usually elevated with a higher incidence of diabetic.

These parameters had left an extremely remarkable change in the iSlim Flat Tummies group of subjects from screening to last visit (day 90), not only within the group but also when compared to placebo group values.

Urine analysis: The Specific gravity, pH, urine color, appearance, pus cells, red cells, epithelial cells had no major changes.

Urine pregnancy test was performed at the time of screening to ensure no women of childbearing potential were enrolled in the trial.

Additional parameters: This study extensively evaluated iSlim Flat Tummies for its activity and efficacy in the weight management segment.

Hs -CRP: In this study the CRP, an anti-inflammatory marker, values were compared amongst the 3 study groups from baseline through all study visits (Table 4/ Graph 2) and the values did not reach any statistical significance amongst the treatment groups towards end of the study (Day 90), however, the iSlim Flat Tummies group showed some minor difference and reduction in the values from its respective screening visit values.

Leptin: This anti-inflammatory /anti-obese marker when compared between the 2 treatment groupsd showed a decrease within the treatment groups but did not show a statistical change between the groups (Table 4/ Graph 2).

Simplified Nutritional Appetite Questionnaire: A set of 4 questions related to simplified nutritional appetite were administered to all study participants. All the study subjects responded voluntarily to this questionnaire as a part of this trial (Table 5 to 8/Graph 2). An average or mean value of the alertness questionnaire score is reflected in Table 9, with a good sign of improvement in the overall appetite of the iSlim Flat Tummies receiving group of subjects.

There were no Serious Adverse Events reported, however, there were 2 AEs noted.

Overheat: A patient-reported on visit 3 on April 28, 2021, from 11:25 hrs to 14:12 hrs self-resolved and may not be related to the IP in the discretion of study investigator.

Gastric pain: - Patient reported on 29-sep-2021 from10:45 to 11:30 self-resolved and may not be related to IP.

There was no protocol deviations observed during the course of the trial. All completed study subjects have 100% compliance with the investigational product.

CONCLUSION:

In this study, iSlim Flat Tummies has demonstrated an excellent safety profile when in the administered orally. Subjects who were mild to moderate range of overweight and received iSlim Flat Tummies showed significant improvement in their fasting and postprandial blood

glucose levels, HbA1c values. Leptin, hs-CRP was better than the placebo group arm at the end of the study (Day 90). These results corroborate even with various cholesterol parameters (LDL, HDL, VLDL, TC and TG) and also with the appetite questionnaire, which shows that the mean/average values of appetite improved in the iSlim Flat Tummies receiving group. This study clearly indicates that iSlim Flat Tummies have significant anti-inflammatory (CRP & leptin) effects in the study subjects as well. Therefore, it is concluded that iSlim Flat Tummies has a definite role in improving the overweight condition along with improving the overall appetite when the subjects administered the product orally for 90 consecutive days.

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