WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 12, Issue 12, 724-734. Research Article ISSN 2277– 7105

FORMULATION AND EVALUATION OF HERBAL EDIBLE GUMMY OF CARRALUMA FIMBRIATA FOR WEIGHT LOSS

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Article Received on
01 June 2023,

Revised on 22 June 2023,
Accepted on 12 July 2023

DOI: 10.20959/wjpr202312-29066

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ABSTRACT

Over the last several decades, there has been an increase in the incidence of obesity, which has led to a pandemic and an increase in other co-morbidities. Numerous factors can contribute to weight increase in an obesogenic environment, therefore medication is one option for treating obesity in addition to more traditional dietary and exercise regimens. There has been a shift to alternative methods as herbal remedies for the treatment of obesity have been studied. Caralluma fimbriata, sometimes known as C. fimbriata, is one such plant extract. The included study was extensively analyzed as well in order to understand more about C. fimbriata's potential effects as an appetite suppressant and weight loss product. **Methods:** According to PRISMA guidelines, a systematic review of clinical research documenting the efficacy of C. fimbriata as an appetite suppressant and anti-obesity supplement was published. Three databases were searched in order to find the information. **Results**: Seven publications on C. fimbriata were found, all of which matched the inclusion and exclusion criteria. They came from different nations, including Australia (3), Cuba (1), India (2), and Spain (1). With the exception of two studies, which recruited healthy persons with an average BMI of 26.5 kg/m2 and the other using a sample of kids and teenagers with Prader-Willis Syndrome (PWS), almost all studies selected people who were overweight or obese with a BMI > 25 kg/m2 (n = 5). A study was conducted to determine the metrics used to measure characteristics of hunger.

KEYWORDS: Caralluma fimbriata, Asclepiadaceae, fat less.

INTRODUCTION

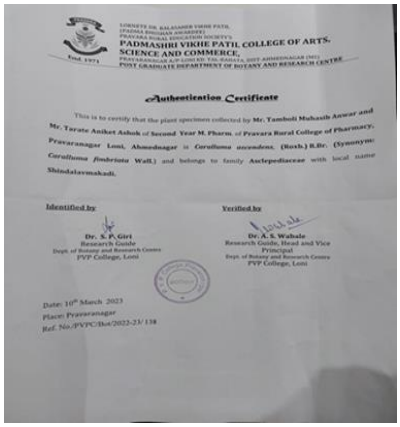
weight problems is commonly defined quite truely as extra body weight for top, but this easy definition belies an etiologically complicated phenotype by and large associated with extra adiposity, or body fatness, which could happen metabolically and no longer just in terms of body size. weight problems substantially increases chance of persistent disease morbidity—namely incapacity, depression, type 2 diabetes, cardiovascular ailment, positive cancers—and mortality. early life obesity consequences within the equal situations, with untimely onset, or with more chance in adulthood . as a consequence, the financial and psychosocial expenses of obesity alone, as well as whilst coupled with these comorbidities and sequealae, are striking.[1] In 2010, overweight and obesity had been expected to purpose three•4 million deaths, 3•nine% of years of lifestyles misplaced, and 3•eight% of disability-adjusted lifestyles-years (DALYs) international. The upward thrust in obesity has led to substantial requires normal tracking of adjustments in overweight and weight problems prevalence in all populations.[2]

Carallumafimbriata is one such Indian herb widely used for obesity in conventional medicine. it's miles an suitable for eating succulent cacti, which belongs to the circle of relatives Asclepiadaceae. it's miles name as a famine meals, urge for food suppressant and grows wild all over India. The scan of literature exhibits few research concerning the efficacy and safety of C. fimbriata in human beings for the control of weight problems and whatever records is available is equivocal. Therefore, the modern-day study changed into undertaken to assess efficacy and safety of C. fimbriata with admire to anthropometric parameters and urge for food suppression in overweight and obese individuals to complement the earlier paintings to reach at conclusive result before it's miles advocated as anti-obesity drug.[3]

MATERIAL AND METHOD

Plant Collection

On November 8th, 2022, the fruit of the Carallumafimbriata, often known as MakadShing, was gathered in Nagpur's Wardha district. Dr. A.S. Webale of the Department of Botany and Research Centre, Science College Loni, University of Pune, India, identified and verified the plant.



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Authentication Certificate

Fig 1: Authentification.

"The plant material was harvested, cleaned, and subsequently dried. For extraction, the dried plant material was pulverized and subjected to Soxhlet extraction using various solvents such as water, methanol, ethanol, and chloroform. Ethanol extraction demonstrated a superior antioxidant profile. The resulting extract was then condensed through distillation. To ensure complete evaporation of the solvents, the extract was further dried in a shaded area. The dried extracts were properly labeled and stored in desiccators for future use. The abbreviations AQS, ETS, MTS, and CHS were used to denote different extracts. Following extraction, the extract was weighed and stored at room temperature.[4]"

Fig No 2: Extraction Assembly.

Preparation of the gummy

Agar and gelatin were used as gelling agents in three separate gummy formulations, each with a different concentration. In the beginning, various concentrations of the gelling agents were tried to get the ideal look, stiffness, and release. The pH is maintained by the use of citric acid. Organoleptic substances were added to the gummy to enhance its visual value. Stevia powder was utilised as a sweetener and bulking agent, and sodium citrate was employed as a preservative. Agar/gelatin, sodium citrate, and citric acid are combined in a

beaker and cooked while being constantly stirred to create the gummy. A sugar solution is made in another beaker and then transferred to the first beaker. The flavouring ingredient and sweetener were combined thoroughly. To prevent exposure to the environment, the dispersion was put into moulds. Wax paper was used to wrap and store the formed gummies.[5-13]

Fig No 3: Gummies.

Characterization of gummy Formulations

The developed weight loss gummy formulations were assessed in accordance with the accepted practises described in the literature**.**

1. Physical Appearance

Clarity, texture, and consistency—three key elements of a nutraceutical formulation—were scrutinised for the gummy formulations' outward appearance.[6]

2. Stickiness and Grittiness

After lightly rubbing a sample of the sativoside gummy between two fingers, the product's stickiness and grittiness were assessed by visual inspection.[6]

3. pH of the soft gummy

The finished gel's pH has a significant impact on both its stability and flavour. At normal temperature, the pH of gummies containing soft gummies was tested using an Electroquip Digital pH metre. Preferably, the pH of the gummy mixture in solution form just prior to gelation is set to 3.0 or higher up to 6.0. This is due to the fact that preparation stability might occasionally worsen and gummy preparations are more likely to trigger syneresis when PH is below 3. The gummy preparation is much more great in stability when the pH is 6 or above

(near to neutrality). Therefore, buffering agents such citric acid and sodium citrate were used to adjust and maintain the PH of the gels' formulations in the range of 3 and 6.[7]

4. Viscosity

Gummy viscosity was determined in triplicate using a Brookfield® viscometer with spindle LV4 at room temperature (25°C 5°C) at a rotation speed of 3 rpm. After cutting a uniform-sized cut on the mould to release the gummies, the viscosity of the substance was measured.[8]

5. In vitro dissolution testing

In vitro dissolution was examined using the USP 28 dissolving Apparatus II (Electrolab Dissolution Tester) in 6.8 pH phosphate buffer (900 mL, 37°C0.5°C) dissolving media at 50 rpm. 10mL samples were collected using a prefilter at 5, 10, 15, 20, 25, 30, 40, and 50 min. The sample was replaced with an equal volume of buffer solution to maintain a consistent volume throughout. Before the materials were evaluated with a UV-Vis Spectrophotometer at 263 nm, they were put through a membrane filter with a 0.5 m pore size. Three times of the process were completed.[9]

6. Content uniformity

The gummy was taken out of the moulds and combined with 0.1 N HCl to create a 100 g/mL solution in a beaker. Using UV-visible spectrophotometric techniques at 263 nm, the sample was examined for drug content after passing through a membrane filter with a pore size of 0.5 m. The process was repeated for each formulation's drug content measurement in triplicate.[10]

7. Weight variation and drug content

In all created gummy formulations, the weight variation was observed to range between 0.99% 1.24 and 1.01% 0.74. The drug content was found to be between 98.23% and 99.25%, which was in compliance with the 98% to 101% pharmacopoeialstandard.[11]

8. Stability studies

According to ICH requirements, stability studies of produced gummies were conducted by storing them at room temperature (25°C 5°C, 75% 5% RH) and at an accelerated temperature (40°C 5°C, 75% 5% RH). The formulation is examined every 30 days for changes in physical parameters such appearance, pH, sugar crystallisation, stiffness, and viscosity throughout the stability investigations, which last for three months.[12]

Fig No 3: Experimental Animal.

EXPERIMENTAL ANIMALS

Swiss albino mice were purchased from Laboratory Animal House, Department of Pharmaceutical Science and Technology, for use in the experimental study. The mice were kept under typical housing circumstances with 12:12 light: dark cycles, humidity between 60 and 65 percent, and room temperatures between 25 and 28 degrees Celsius. Before beginning the trial, they were habituated for seven days.[14]

HFD composition

Mice were given a high-fat diet (HFD) containing casein (299.0 g/kg), lard (315 g/kg), butter oil (185 g/kg), L-cystine (3.35 g/kg), corn oil (18.0 g/kg), corn starch (210.5 g/kg), sucrose (95.6 g/kg), dextrose (120.8 g/kg), cellulose (55 g/kg), vitamin mix.[15]

Drugs and treatment

Standard drug - Orlistat 5mg/kg b.

Test drug - Carallumafimbriata gummy

Group-1

(Normal control): Mice that were raised in a typical environment and fed a typical diet.

Group-2

(Obese control): Mice that had grown obesity after being fed an MSG-HFD diet were chosen.

Group-3

(Standard treatment): Obesity caused by MSG-HFD was treated with the common medication orlistat tablets (5mg/kg/day, for 21 days).

Group-4

(Test treatment): obese mice were given 500 mg of carallumafimbriata gummy extract twice daily for up to 12 weeks.[15-16]

Measurement of Body Weight

Weekly bodyweight calculations and comparisons were done throughout the 12-week trial periods.

Effect on body weight

When compared to the obese control group, it was shown that the STD, carallumafimbriata gummy group's animals showed a highly substantial reduction in body weight, reaching body weights comparable to those of normal animals. (Table no 6).

Table 1: Rf value of crude extracts of Caralluma fimbriata.

Sr no	Test extract	Rf value
1	Aqueous extract	0.6
2	Chloroform extract	0.5
3	Methanol extract	0.7
4	Ethanol extract	0.8

Table 2: Formulae of herbal edible gummy.

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Herbal Extract	PPZ	AQS	CHS	ETS	MTS	AQS	CHS	ETS	MTS
Agar		3%	3%	3%	3%				
Gelatin	4.5%					4.5%	4.5%	4.5%	4.5%
Stevia Powder	70%	70%	70%	70%	70%	70%	70%	70%	70%
Sodium Citrate	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
Citric Acid	2%	2%	2%	2%	2%	2%	2%	2%	2%
Glycerine	0.6%	0.6ml	0.6ml	0.6ml	0.6ml	0.6ml	0.6ml	0.6ml	0.6ml
Flavouring Agent	1ml	1ml	1ml	1ml	1ml	1ml	1ml	1ml	1ml
Water	q. s	q. s	q. s	q. s	q. s	q. s	q. s	q. s	q. s

Table 3: Physical properties of oral edible gummy.

Sr. No	Formulation code	Colour	Texture	PH	Stickiness	Viscosity
1	F1	Light Brownish	Smooth	3.40±0.18	Non-sticky	55600
2	F2	Light Brownish	Smooth	3.50±0.15	Sticky	36545
3	F3	Brownish	Smooth	3.40±0.20	Sticky	32765
4	F4	Brownish	Smooth	3.42±0.2	Sticky	35546
5	F5	Brownish	Smooth	.70±0.15	sticky	40987
6	F6	Dirty Brownish	Smooth	.70±020	Non-sticky	62087
7	F7	Brownish	Smooth	3.65 ±0.2	Sticky	57843
8	F8	Brownish	Smooth	0.60±0.15	Non-sticky	64961
9	F9	Brownish	Smooth	5.2 0±.05	Non-sticky	55321

Table 4: Drug Content and release data edible gummy.

Sr. No	Formulation Code	%Drug Content	%Drug Release
1	F1	92.87±0.05	90.76±0.15
1	F2	86.87±0.11	93.32±0.21
2	F3	86.78±0.87	90.31±0.15
3	F4	90.61±0.31	95.86±0.84
4	F5	88.54±0.12	93.54±0.45
5	F6	93.42±0.35	94.65±0.65
6	F7	96.92±0.50	92.67±0.54
7	F8	94.43±0.19	98.98 ±0.53
8	F9	93.61±0.64	93.87±0.77

Table 5: Stability study data of the edible gummy.

Formulation	Characteristics	30 days	60 days	90 days
F4	Appearance	Smooth	Smooth	Smooth
	PH	3.65±0.053	3.55±0.06	3.30±0.08
	Viscosity	62650	61985	60321
F5	Appearance	Smooth	Smooth	Smooth
	PH	3.7±0.09	3.5±0.07	3.76±0.08
	Viscosity	65521	63543	60021

Table No 6: Changes in body weight during treatment period.

GROUPS	NOR.CON	OB.CON	STD	OS
Day1	24.51±0.12	52.01±0.25^{c}	48.30 ±0.04^{c,***}	48.25±0.06^{c,***}
Day4	24.48±0.11	52.48±0.04	46.95±0.08^{C,***}	46.72±0.14^{c,***}
Day8	25.68±0.18	52.64±0.11^{c}	40.72±0.06^{c,***}	43.83±0.13^{c,***}
Day12	25.72±0.18	51.98±0.07^{c}	35.83 ±0.07^{c,***}	41.93±0.12^{c,***}
Day16	25.05±0.09	51.97±0.10^{c}	30.93 ±0.10^{c,***}	36.74±0.08^{c,***}
Day20	25.65±0.12	51.65±0.05^{c}	27.07±0.11^{c,***}	39.94±0.07^{c,***}

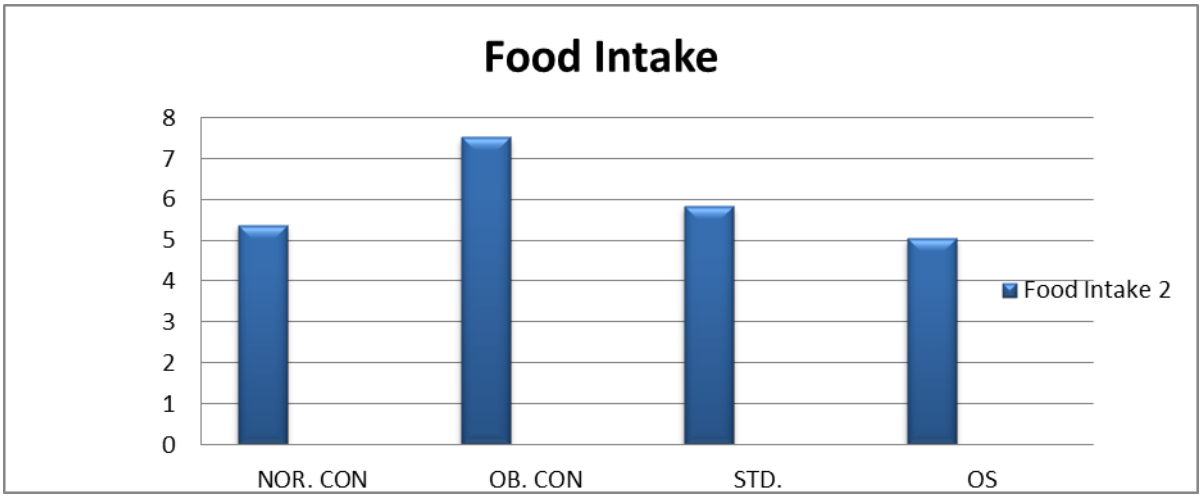

Table No 7: Change in food intake among different group.

DISCUSSION

Soxhlation turned into used to extract the Carallumafimbriata dried leaves the usage of a ramification of solvents, consisting of water, ethanol, methanol, and chloroform. After drying, the extract was tested for its phytochemical components. The preliminary phytochemical screening outcomes confirmed that saponin, phenol, alkaloids, anthraquinones, carbohydrates, steroids, coumarin, and quinones had been present. The fit to be eaten gummies have been made through jelling several carallumafimbriata extracts with gelatin and agar. The sweet was visually examined. The gelatin-based gummies (F6-F8) had a rigid, translucent texture and a pleasing appearance. the usage of a virtual pH metre, the pH of every system changed into measured, and all the formulations had a pH between 3.1 and five.nine. the use of Brookfield viscometer, the viscosity of each formula changed into decided. The findings confirmed that formulations F2-F5, which have low viscosity, and formulations F1, F6–F9, which are made with gelatin, had been located to have a uniform consistency. using a UV-visible spectrophotometer, the amount of medicine in fit to be eaten gummies that have been synthetic became expected. utilising zero.1 N HCl, the medicine contained inside the edible gummyu was removed. After filtering, the sample's anticipated wavelength turned into 263 nm.Dissolution apparatus kind i used to be used to hold the amount of drugs release from the gummy. the use of a paddle device, the in vitro drug launch from the gummy became estimated. It was expected how much drug can be launched. when compared to different formulations, the F8 components showed the most drug release. The formulations' capability to combat weight problems became assessed. The formula F8 and not unusual remedy formula were contrasted. For the stability investigations, a formulation with strong anti-weight problems houses and rapid dissolution turned into employed. In a controlled placing, balance checking out on the synthetic gummies happened over the route of 3 months. every three days, the viscosity, pH, and appearance of the gummy were assessed. The outcomes confirmed that the viscosity, pH, and look of the revised method did no longer trade.

CONCLUSION

In this study, agar and gelatin were used to successfully create edible gummies that were filled with different caralluma fimbriata extracts. The edible gelatin gummies had a firm texture and appealing appearance. The improved formulation F8 displayed respectable physico-chemical characteristics as well as strong stability. The formulation demonstrated effective anti-obesity efficacy and can be used in place of oral solid dose forms.

REFERENCE

1. Hruby A, Hu FB. The Epidemiology of Obesity: A Big Picture. Pharmacoeconomics, 2015 Jul; 33(7): 673-89. doi: 10.1007/s40273-014-0243-x. PMID: 25471927; PMCID: PMC4859313.
2. Ng M, Fleming T, Robinson M, Thomson B, Graetz N, Margono C, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980–2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet [Internet] (0). Available from: http://www.sciencedirect.com/science/article/pii/S0140673614604608. [PMC free article] [PubMed]
3. Arora E, Khajuria V, Tandon VR, Sharma A, Mahajan A, Gillani ZH, Choudhary N. To evaluate efficacy and safety of Carallumafimbriata in overweight and obese patients: A randomized, single blinded, placebo control trial. PerspectClin Res, 2015 Jan-Mar; 6(1): 39-44. doi: 10.4103/2229-3485.148812. PMID: 25657901; PMCID: PMC4314845.
4. Syed AbubakkarSiddiq S, Anusha S and Sathish S. UV, FT-IR, and GC-MS analysis of Carallumafimbriata. J PharmacognPhytochem, 2021; 10(5): 288-291.
5. N.L. PRASANTHI*, P. NANDINI, S.S. MANIKIRAN, N. RAMARAO.D esign and Development of Herbal Pediatric Edible.J. Pharm. Sci, 2019; 11(6): 2417-2421.
6. Mangesh D Godbole, DebarshiKarMahapatra, Priya D Khode. Fabrication andCharacterization of Edible Jelly Formulation ofStevioside: A Nutraceutical or OTC Aid for the DiabeticPatients. Inventi Rapid: Nutraceuticals, 2017; 2: 1-9.
7. Mishra, Manoj. (2016). Formulation And Evaluation Of Oral Soft Jelly Containing Glibenclamide. 10.5281/zenodo.167095.
8. Ines Ben Rejeb, NahlaDhen, Salma Kassebi, Mohamed Gargouri, "Quality Evaluation and Functional Properties of Reduced Sugar Jellies Formulated from Citrus Fruits", Journal of Chemistry, vol. 2020, Article ID 5476872, 8 pages, 2020.
9. Sushil D. Patil, Mukul J. Gupta, Kaustubh S. Kote, Mr. Rajendran R. Formulation of Novel Medicated Jellies for Treatment of Mouth Ulcer. Asian J. Pharm. Tech, 2019; 9(4): 241-243. doi: 10.5958/2231-5713.2019.00039.4.
10. Sarangapani, Sarojini&Anusha, Kandula&Maneesha, Ch&Mufaquam, M &. B, Deepika& Reddy, Y &., Naga RajuKandukoori. (2018). ORAL MEDICATED JELLIES - A REVIEW *Corresponding Author. 10.20959/wjpr20186-11502.
11. Paras B. Pophalkar*, R. B. Wakade, Sachin U. Hole, Chetan Y. Kadam, Rajnandni S. Suroshe and Wrushali A. Panchal. DEVELOPMENT AND EVALUATION OF

ONDANSETRON MEDICATED JELLY. World Journal of Pharmaceutical Research, 2018; 7(19): 1252-1263.

12. HamedAlmurisi S, Al-Japairai K, Alshammari F, Alheibshy F, Sammour RMF, Doolaanea AA. Stability of Paracetamol Instant Jelly for Reconstitution: Impact of Packaging, Temperature and Humidity. Gels, 2022 Feb 25; 8(3): 144. doi: 10.3390/gels8030144. PMID: 35323257; PMCID: PMC8950020.
13. SamikshaDilipkumarJayswal*, NirmalaChhitarmalKumawat, Shivani Kailas Jaiswal, Vaishnavi Parashuram Kandhare, SulbhaPatil and Dr. S. P. Pawar. FORMULATION AND EVALUATION OF HERBAL ORAL MEDICATED JELLIES OF GLYCYRRHIZA AND SPEARMINT.EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH, 2022; 9(6): 302-312.
14. Talbot SR, Biernot S, Bleich A, et al. Defining body-weight reduction as a humane endpoint: a critical appraisal. Laboratory Animals, 2020; 54(1): 99-110. doi:10.1177/0023677219883319.
15. Mopuri, R., Ganjayi, M., Banavathy, K.S. et al. Evaluation of anti-obesity activities of ethanolic extract of Terminaliapaniculata bark on high fat diet-induced obese rats. BMC Complement Altern Med, 2015; 15: 76. https://doi.org/10.1186/s12906-015-0598-3.
16. Dourish, Colin & Wilding, John & Halford, Jason. (2008). Anti-obesity Drugs: From Animal Models to Clinical Efficacy. 10.1016/B978-0-12-373861-5.00028-X.