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A RESEARCH ON FORMULATION AND EVALUATION OF HERBAL CAPSULE OF HIBISCUS ROSA SINESIS

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ABSTRACT

Traditional treatment for number of illness including obesity use teas made from Hibiscus Rosa sinesis. The goal of the current study was to evaluate the effect of polyphenol rich herbal plant extract on obesity and associated by a chemical parameter in that had been made obese by a high fat, sugar- diet Hibiscus Rosa sinesis was found to include tannin anthraquinones, quines, phenol, flavonoids, alkaloid, terpenoids, saponnins, cardiac glycosides, protein, free amino acids, carbohydrates, reducing sugar, mucilage, essential oil, and steroid according to the phytochemical examination. Hibiscus Rosa sinesis has been found to be have reproductive , antidibetic, fibrinolytic, anti- inflammatory, anti-pyretic, analgesic, immunomodulating, hypolipidemic anti-depressant, anti-oxidant, cytotoxic, dermatological, memory improving, impact on the brain the liver the immune system. It can conclude from these result the Hibiscus Rosa sinesis exhibited strong protective effect against obesity and oxidative stress.

KEYWORDS: Hibiscus Rosa sinesis, Phenolic acid, Flavonoid, Therapeutic use, Obesity.

Fig: Hibiscus Rosa sinesis.

Introduction

Scientific classification

Common name : Hibiscus, Coopri. Auct.
Scientific name : Hibiscus rosa-sinensis.
Kingdom : Plantae.
Subkingdom : Tracheobionta.
Division : Magnoliophyta.
Subdivision : Spermatophyta.
Class : Magnoliopsida.
Subclass : Dilleniidae.
Order : Malvales.
Family : Malvaceae.
Genus : Hibiscus.
Species : rosa-sinesis.

Chemical constituents

Tannins, anthraquinones, quinines, phenols, flavonoids, alkaloids, terpenoids, saponnins, cardiac glycosides, proteins, free amino acids, mucilage essential oils, and steroids.

Taxonomy and Morphology

Hibiscus rosa sinesi was firstly described by in 1753 by Carl Linnaeus, in species plantarum, and family of Hibiscus is Malvaceae. Hibiscus rosa-sinesis is one of the many plant species with genetic characteristics known as polyploidy, a condition in which the species has more than two complete sets of chromosomes. It is mostly found in South East China and few Island, in the pacific, and Indian oceans.

Hibiscus species is also known as "Queen of the Tropics" or "The China Rose". Hibiscus flower derived juice has been used for many years as a natural treatment for several disease and excruciating symptoms. The aim of the hibiscus flower is weight loss. These plant contains anthocyanin, phenolic compound and flavonoid that can help to regulate the genes involved in fat digestion. Which can boost fat elimination these substance also help to manage fat cell hypertrophy, by reducing the size of fat cell. The anti-oxidant mechanism of the anthocynin typically include the suppression of relative species formation through enzyme inhibitor or the sequestration of trace elements involved in the production of free radical significantly better lipid profile and reduced glucose. Total cholesterol and low density lipoprotein while increasing high density lipoprotein.

Phenolic extract worked by inhibiting the digestive enzyme that in turn reduce digestion of carbohydrates and fat lowering the energy intake.

Powder

Definition: Finely divided powder that contain one or more medication, with or without axillary substance including where specific coloring and flavoring agent. They are intended to be taken internally with or without aid of water or any suitable liquid.

Fig: Powder of Hibiscus.

Properties Of Powder

1) Fundamental properties

Particle size and distribution.
Particle volume.
Particle number.
Particle shape.
Surface area.

2) Derived Properties

Porosity.
Density.
Bulkiness.
Flow property.

Granules

Definition: Powder particles that have been aggregated to form larger free flowing particle usually 2 to 4 mm.

Granules used in the production of tablet or capsules, also used as medicated dosage form such as effervescent granules. Granule contain one or more active substance with or without excipient and if necessary coloring matter authorized by competent authority and flavoring substance.

Fig. Hibiscus Granules.

Method of Granulation

Direct compression method
Dry Granulation method
Wet Granulation method

Wet Granulation Method

Wet granulation involves the preparation of mass of a mixture of a dry powder using granulating method. The granulation fluid contains a solvent which must be non toxic and volatile, so tat it can be removed by drying. (Example – Water, ethanol and isopropanol either alone or combination). The granulation liquid used as it or an adhesive is dissolved in it to ensure particle adhesion once the granules is dried.

Water is commonly used for economic and ecological reason, The primary advantage of water is that it is non flammable which means that expensive safety precaution such as use of flameproof equipment need not be taken. It disadvantage are that it may adversely affect drug stability causing hydrolysis of susceptibility product and it need a longer drying time than to organic solvents. The increase the length of the process and may again affect stability because of the because of extended exposure to heat. Organic solvents are used for water sensitive drug. They are preferred when a rapid drying time is required. After forming a coherent or drug using a granulating fluid. The wet mass is forced through a sieve to produce wet granules then dried. The dried granules are screened (a passed through a sieve).

Fig. Wet Granulation for Hibiscus.

Capsules

The termed capsule is derived for Latin word ‘capsule’ meaning a small container.

Define: Capsule are solid dosage form in which the drug substance is enclosed within either hard or soft soluble shell usually from gelatin.

Fig: Hibiscus capsule.

Types of Capsules

Hard Gelatin Capsule

Disintegration time is 30 minutes, made from gelatin + sugar + water + dried filled capsule.

Soft gelatin capsule

Disintegration time is 60 minutes is made up from gelatin + plasticizer + water.

Soluble elastic and soft elastic capsule, liquid filling capsule.

Methodology

A) Drug and Polymeric profile

Hibiscus powder: Take dried hibiscus powder, weight amount a hibiscus powder.

Diluent: Lactose.

Lactose is a sugar that is naturally found in milk and milk product. Soluble diluent in formulation due to its excellence flow ability and compressibility. As well as rheological properties.

Guidant: Corn starch.

To enhance the Flow ability, thickening agent for gravis source mainly used in tablet and capsule formulation.

Lubricant: Steric acid.

Widely used in lubricant in oral tablet, granules and capsules.

Disintegrates: Sodium alginate.

Promote the break up of the tablet, capsule into smaller fragment in an aqueous media.

Solvent: Ethanol.

Ethanol is most widely used solvent. Solvent is used as a granulating agent at the slugging point.

Surfactant: Sodium laurel sulphate.

To reduce the surface tension. SLS is the anionic surfactant.

Binder: Acacia.

Acacia is mostly used as binder to enhance the cohesiveness of powder strong bonding formation.

B) Extraction

Species of Hibiscus rosa sinensis. Amount of required petals extracted from flowers a dried petals and then crushed to form fully dried powder.

Composition of Granules Formulation

parameters	Quantity given	Quantity Taken
Hibiscus Powder	20 gm	20 gm
Lactose	10gm	6.2 gm
Corn starch	10 gm	1.9 gm
Steric acid	1 ml	0.9 ml
Sodium Alginate	2 gm	0.3 gm
Surfactant	3gm	2.1 gm
Acacia	2 gm	1.2 gm

Fig. Formulation Table.

Take a quantity of hibiscus powder is the actual pharmaceutical active ingredient. The main purpose of hibiscus is the reduce weight. Hibiscus contains a anthocyanin flavonoids and phenols. This constituents is useful for the inhibit the digestive enzyme that turn in reduce digestion of carbohydrate and fat lowering Required quantity of drug and excipient take accurately like glidant, dilunt etc. Material is ready for mixing firstly hibiscus powder and lactose is mixed with help of mortar and pestle then add corn starch, enteric acid sodium alginate acacia, and sodium lauryl sulphate proper mixing is done.

The to make a 5% starch slurry starch slurry drop wise added in mortar and then mixed continuously. Ethanol is used as granulating agent. According to the mixture then required according to the mixture then required amount of ethanol is added then wet screening is done and addition of binder properly then the bulk mass produced . This bulk mass dry at 10-15 minute. This mass transferred to the tray line with the butter paper and granule are kept for drying in hot air oven at 55c for 15-20 minute. After 15 minute granule are checked to drying. Take empty shell of hard gelatin capsule. The size of capsule 50000 capsule size is mostly used in marketed preparation. Weighing of the granule and exact amount of granule to fill the capsule shell and then seal the capsule shell and then seal the capsule top or bottom part of hard gelatin capsule.

Evaluation tests

A) Weight variation test: 20 Capsules are individually weighed and average weight determined.

- Test is passed: If all capsules individual weight is less than 90% and more than 110% of average weight.
- If the original 20 do not meet these criteria the individual net weight is determined.
- These are a and averaged and differences are determined between each individual net content and the average.
- If not more than 2 of the individual differences are greater than 10 % of the if in case any difference is greater than.

If more than 2 but less than 6 net weight determined by the test devia by more 10 % but less than 25 % .The net content is determined for additional 40 capsules and the average is calculated for the entire 60 capsules. 60 deviation from the new average are calculated.

% Variation	USP
± 10%	Weighing 130 mg or less
± 75%	Weighing 130 – 324 mg
± 5%	Weighing 324 mg or more

Moisture permission test: This test is carried out to assure the suitability of container for packaging of capsule. The moisture promoting feature of capsule packaged in single unit container – blister pack or strip pack. Unit dose container glass or plastic bottle is to be determined.

B) Content uniformity

30 capsules selected 10 Assayed
Test is passed
If 9 capsules are in range i.e. 85 % to 115 %
1 is not outside the 75 % to 125 %

If more than 1 but less 3 of the first 10 capsule outside the 85 % to 115 % limit.
20 Capsule assayed (Test is passed if)
All 30 capsules are within 75 % to 125 % of the specified potency range. But not less than 27 from 30 within 45 % tolls range.

C) Dissolution test

It is the official method to determine the dissolution of a solid dosage form.

Apparatus: Rotating Basket apparatus.

Place 1000 ml of water free from dissolved air having temperature of 36 ^{0}C to 37 ^{0}C in to the vessels. Place the specified number of capsule in a dry basket. Start the motor and adjust its speed 150 rpm. Withdraw the required volume of solution from the vessel after 45 minutes or after period specified. Filter and determined the amount of active ingredient present by the method. Repeat the complete operation 4 time. Sample passes the test is amount of active ingredient in the solution is not less than 70 % of stated amount in given sample.

D) Disintegration test

This test evaluate the rate of disintegration of solid dosage form. Hard gelatin capsule is the 15 minutes hard shell piece after disintegration may agglomerate forming large mass of gelatin taking more time to dissolved and may added to the mesh blocking the holes according to USP place one dosage unit in each of the tubes of the basket with water or any other specified medium maintained at 37.30^{c}c.

Observe the capsule for a time limit at the end of prescribing time on the capsule must have been disintegrated excluding the fragments from the capsule shell. 1 or 2 capsule fails the test should be repeated on addition 12 capsule. Not fewer than 16 of the total 18 capsule tested should disintegrate completely.

Fig: Disintegration test.

RESULT

The present work aimed to the formulation and evaluation of herbal capsule successfully completed.

Hibiscus flower is used in a formulation. The species of rosa sinesis contain anthocyanin, flavonoids, saponin, free amino is used to reduce weight.

Formulation of hard gelatin capsule was characterized by good bioavailability, better stability and solubility.

Characteristics	Observation
Physical appearance	Hard gelatin capsule
P^H	4 – 6.8
Colour	Pink
State	Solid
Solublity	Good
Disintegrtion time	15 Minutes
Bioavaliablity	Good

SUMMARY

Rosa sinesis is the species is used to reduce weight. Rosa sinesis contain flavonoid, anthocyanin, to reduce triglycerides fatty acid. Hibiscus is also used as an herbal medicines for weight loss. Hibiscus powder is mix with suitable granulating agent to improve flow ability compressibility. Wet granulation method is most preferable for capsule. Formulation of granule with the help of proper sieve size and granule is formed. Granule is filled in hard gelatin shell.

CONCLUSION

It can be concluded from the present investigation that selection of hibiscus species of rosa sinesis content flavonoid saponin anthocyanin. Rosa sinesis is the strong protective effect against obesity. hard gelatin capsule is type of capsule that is usually used to contain medicine in the form of granule. However the formulation of herbal capsule is showed the high percentage bioavailability, solubility and effective to the reduce fat in body

REFERENCE

1. Dafallah AA, al-Mustafa Z. Investigation of the anti-inflammatory activity of Acacia nilotica and Hibiscus sabdariffa. Am J Chin Med, 1996; 24: 263-9.
2. Onyenekwe PC, Ajani EO, Ameh DA, Gamaniel KS. Antihypertensive effect of roselle (Hibiscus sabdariffa) calyx infusion in spontaneously hypertensive rats and a comparison of its toxicity with that in Wistar rats. Cell Biochem Funct, 1999; 17: 199 - 206.
3. Herranz-Lopez, M. et al. Synergism of plant-derived polyphenols in adipogenesis: perspectives and implications. Phytomedicine, 2012; 19: 253–261.
4. Shirwany, N. A. & Zou, M. H. AMPK: a cellular metabolic and redox sensor. A minireview. Front. Biosci. (Landmark Ed), 2014; 19L 447–74.
5. Carling, D. AMPK signalling in health and disease. Curr. Opin. Cell Biol., 2017; 45: 31–37.
6. Barrajón-Catalán, E. et al. Molecular promiscuity of plant polyphenols in the management of age-related diseases: Far beyond their antioxidant properties. Adv. Exp. Med. Biol., 2014; 824: 141–159.
7. Yeop Han et al. Differential effect of saturated and unsaturated free fatty acids on the generation of monocyte adhesion and chemotactic factors by adipocytes: dissociation of adipocyte hypertrophy from inflammation. Diabetes, 2010; 59: 386–96.
8. Iyer, A. et al. Inflammatory lipid mediators in adipocyte function and obesity. Nat. Rev. Endocrinol, 2010; 6: 71–82.
9. Furukawa, S. et al. Increased oxidative stress in obesity and its impact on metabolic syndrome. J. Clin. Invest, 2004; 114: 1752–61.
10. Beltran-Debon, R. et al. The aqueous extract of Hibiscus sabdariffa calices modulates the production of monocyte chemoattractant protein-1 in humans. Phytomedicine, 2010; 17: 186–191.
11. Fernandez-Arroyo, S. et al. Bioavailability study of a polyphenol-enriched extract from Hibiscus sabdariffa in rats and associated antioxidant status. Mol. Nutr. Food Res., 2012; 56: 1590–1595.
12. Olivares-Vicente, M. et al. Plant-derived polyphenols in human health: biological activity, metabolites and putative molecular targets. Curr. Drug Metab., 2018; 19: 351–369.
13. Herranz-Lopez, M. et al. Correlation between the cellular metabolism of quercetin and its glucuronide metabolite and oxidative stress in hypertrophied 3T3-L1 adipocytes. Phytomedicine, 2017; 25: 25–28.
14. Herranz-Lopez, M. et al. Lemon verbena (Lippia citriodora) polyphenols alleviate obesity-related disturbances in hypertrophic adipocytes through AMPK-dependent mechanisms. Phytomedicine, 2015; 22: 605–614.
15. Herranz-Lopez, M. et al. Lemon verbena (Lippia citriodora) polyphenols alleviate obesity-related disturbances in hypertrophic adipocytes through AMPK-dependent mechanisms. Phytomedicine, 2015; 22: 605–614.
16. Kannel WB, Castelli WP, Gordon T, McNamara PM. Serum cholesterol, lipoproteins, and the risk of coronary heart disease. Ann Intern Med, 1971; 74: 1-12.
17. Keys A. Coronary heart disease in seven countries. Circulation, 1970; 41: 1-211.
18. Glade MJ. Food, nutrition, and the prevention of cancer: a global perspective.American Institute of Cancer Research/World Cancer Research Fund. Nutrition, 1999; 15: 523 - 6.
19. Klerk M, Jansen MC, van't Veer P, Kok F. Fruits and vegetables in chronic disease prevention.

Wageningen7 Wageningen Agricultural University, 1998.
20. Steinmetz KA, Potter JD. Vegetables, fruit, and cancer prevention: a review. J Am Diet Assoc, 1996; 96: 1027 - 39.
21. Morton LW, Abu-Amsha CR, Puddey IB, Croft KD. Chemistry and biological effects of dietary phenolic compounds: relevance to cardiovascular disease. Clin Exp Pharmacol Physiol, 2000; 27: 152 - 9.
22. Visioli F, Borsani L, Galli C. Diet and prevention of coronary heart disease: thepotential role of phytochemicals. Cardiovasc Res, 2000; 47: 419 - 25.
23. Lampe JW. Health effects of vegetables and fruit: assessing mechanisms of action in human experimental studies. Am J Clin Nutr, 1999; 70: 475S - 90S.
24. Tsuda T, Kato Y, Osawa T. Mechanism for the peroxynitrite scavenging activityby anthocyanins. FEBS Lett, 2000; 484: 207 - 10.
25. Ramirez-Tortosa C, Andersen OM, Gardner PT, Morrice PC, Wood SG, Duthie SJ, et al. Anthocyanin-rich extract decreases indices of lipid peroxidation and DNA damage in vitamin E-depleted rats. Free Radic Biol Med, 2000; 31: 1033 - 7.