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Research Article

Formulation and Development of Herbal Dosage Form for Antidiabetic Activity

Romila Oskar,Mithun Balmik,Dr Pankaj Tiwari.

Millennium College of Pharmacy, Bhopal , M.P., India

Abstract

Diabetic mellitus is chronic disease that is associated with long term complication. This research gives information regarding the herbal drugs will cure the diabetic complication in patient. Herbal antidiabetic drug treat diabetic mellitus by lowering glucose level in blood and they increase the insulin amount secreted by the pancreases. In this research mostly the garlic shows the antidiabetic action in that garlic the allion is chemical component responsible to decrease glucose level in blood. When the diabetic patient getting affected by any type of injury then the neem is act as wound healing property and also it has anti-hyperglycaemic activity. In this research we were formulated herbal antidiabetic drug from Carrisa carandus and Manilka ra zapota .and evaluation were perform such as disintegration test, Dissolution test, Hardness test, angle of repose and friability test.

Keywords : Antidiabetic, Formulation of tablet, Evaluation, Garlic, Carrisa carandus .

Introduction

Herbal medicine is the oldest form of healthcare known to mankind. Herbs had been used by all cultures throughout history. It was an integral part of the development of modern civilization. They methodically collected information on herbs and developed well-defined herbal pharmacopoeias. Indeed, well into the 20th century much of the pharmacopoeia of scientific medicine was derived from the herbal lore of native peoples. The World Health Organization (WHO) estimates that 4 billion people, 80% of the world population presently use herbal medicine for some aspect of primary healthcare. Herbal medicine is a major component in all indigenous peoples'traditionalmedicineandacommonelementinAyurvedic,Homeopathic,naturopathic,traditional oriental, and Native American Indian medicine. It has been estimated that70-90%oftheworld'spopulationreliesonalternativetherapiesandpractices.Herbals are used in the art of healing since the time immemorial. The primitive man through trial and error gained knowledge of herbal and passed it onto the next progeny. It is reasonable to assume that for ten thousands of year herbs were perhaps used for the magical power as well as for the irmedicinal values.

Diabetes mellitus is a chronic metabolic disorder resulting from insulin deficiency, characterized by hyper glycaemia, altered metabolism of carbohydrates, protein and lipids, and an increased risk of vascular complication. The insulin deficiency may be absolute or relative and the metabolic abnormalities lead to the classic symptom of polyuria, polydipsia, polyphagiaand fatigue.[1-5]

Corresponding Author

E.mail:shailgpharma@gmail.com

Materials and Methods[6-11]

Authentication and Collection of Plant Materials

The selected plants, Carrisa carandus (SRK/CA-0516), Manilkara zapota (SRK/MZ-0312), were collected from local area of Bhopal (M.P.). The Leaves of all plant drugs were shade-dried, powdered into moderately coarse powder and stored in air tight container. Plant specimens were identified and authenticated in SAIFIA College, Bhopal. The powder drug of all plants material was used for extraction.

Extraction of Plant Materials :

The powdered drug of Carrisa carandus plant (about 150 gm) was defatted with petroleum ether and extracted with methanol (95%) in a soxhlet apparatus for 12 and24 Hrs respectively. The solvent was removed under reduced pressure, with respect to dried plantmaterial. The dried extract of was stored in adesiccator till further use. The powdered drug of Manilkara zapota plant (about 150 gm) was defatted with petroleum ether and extracted with methanol (95%) in a soxhlet apparatus for 12 and30 Hrs respectively. The solvent was removed under reduced pressure, with respect to dried plant material. The dried extract of was stored in adesiccator till further use.

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Formulation of Poly Herbal Tablets: The dried plant extracts of all proposed plants were mixed with different excipient using wet granulation method to prepare later solid pharmaceutical forms. These prepared granules of each form were compressed into tablets using Compressing machine.

Granulation of ingredients:

The wet granulation technique was selected because it is always better for small-scale preparations. The standardizedex tracts an do ther in gredients for each formula were weighed, ground and screened through sieve no. 80 separately.Allthematerialsweremixedtogetherexcept Talcand magnesiumstearatemilledinapestle mortar and sieve dagain through sieve no. 80.The materials were mixed with the binder solution, which was added little by little. After well mixing,thepowdermasswasscreenedthroughsieveno.18togetthegranulesandtheywere dried well at 35°C in vacuum dryer. After drying, the granules were againscreenedthroughsieveno.18toremovebiggergranulesandstoredindesiccator. All the poly herbal extracts and excipient mixture were subjected to pre-formulation studies according to standard recommended procedure before punch in tablets.

Punching of granules

Punching of the tablets was carried out in our working laboratory. Hand rotating single punch machine was used ,the punch was concave and its diameter was1cm.The granules were mixed with talc and magnesium stearate and it was ready for punching. The die cavity was adjusted for required weight and the granules were punched to tablets. The weight variation and hardness of punched tablets were checked intermittently.

Table 1.1 Composition of Poly herbal tablet formulation

Ingredients	Quantity per tablet(mg)			
	F1	F2	F3	F4
CarissaCarandus	100	100	100	100
ManilkaraZapota	100	100	100	100
Ethyl Cellulose	50	40	40	30
Micro crystalline Cellulose	40	40	40	40
Dibasiccalcium phosphate	30	40	30	50
PEG400	20	10	20	20
Methyl paraben	10	20	20	10
Weight per tablet	550 mg	550 mg	550 mg	550 mg

EVALUATION OF FORMULATED GRANULES AND TABLETS

Particle size

Size affects the average weight of tablet. The method used for determination of particle size is Sieving(No 20).

Angle of repose

Using the funnel technique, the angle of repose was determined. In a funnel, the precisely weighed mix was drawn. The drug excipient mixture was permitted to flow freely to the surface through the funnel (Lakade and Bhalekar, 2008). The funnel height has been adapted in such a manner that the funnel tip just touches the heap or mix head apex. Measured the diameter of the powder cone and calculated the angle of repose using the following formula:

$\tan\theta = h/r$

Where, h = height of powder cone formedr=radius of the powder coneformed

Loose bulk density

Loose bulk density was determined by a simple method in which a weighted amount of mixture was poured into a graduated cylinder and we were measure the exact volume and weight of the mixture (Aulton, 2002).

LBD=Weight of the powdered material/volume of packed material

Tapped bulk density

A graduated cylinder comprising a known mass of drug excipient mixture was used to determine tapped density. The cylinder was permitted to drop from the height of 10cmattwosecondsunderitsownweightontoadifficultsurface.(Bankerand Anderson,1987).The process was repeated until no further change in volume was observed.

TBD=Weight of the powdered material/vol of the tapped packing material

Compressibility index

TheCompressibilityindexoftheblendswasdeterminedbyCarr's compressibilityindex (Mohsin et al., 2010).

Compressibility index(%)=(TBD-LBD)x100/TBD

Hausnerratio

Itisthedrug'sfrictionalresistancemeasurement.1.2-1.5 is the standard range of Hausnerratio(Hamidetal.,2006). The following formula is used to determine it:

Hausnerratio =TBD/LBD

Weight variation test

With a tablet designed to contain a specific amount of drug in a specific amount of tablet formula, the weight of the tablet being made is routinely measured to ensure that a tablet contains the proper amount of drug. By randomly choosing and weighing20 tablets, the average weight was determined. Each tablet was separately weighed as well. In each case, the difference from the average weight was calculated and expressed as a percentage.

All the values shown in table 1.4 and according to USP limit for the test, not more than 2 tablets were outside the percentage limit and no tablet differs by more than 2 times the percentage limit (□5%). The prepared tablets passed the limit.

Hardness and Friability test

Tablets require a certain amount of strength or hardness and resistance friability, to with stand mechanical shock so fhandlingin all processes. The hardness and friendliness of the tablets were evaluated using respectively calibrated hardness testers(Monsanto) and Roche friabilitor (4 minutes at 25 rpm). The friability of tablets for all formulations, were determined by Roche friabilator. The tablets was weighed and put in to the plastic chamber and operated for 100 revolutions. Then, the tablets were dusted and reweighed. The percentage friability was calculated for each formulation and the values were given in table 1.4. The tablets passed the acceptable limit lessthan1%.

Disintegration test for tablets

The disintegration time of tablet for all formulations was determined by using the IP disintegration apparatus(IndianPharmacopoeia,1996).The900mlof0.1Nhydrochloricacidwasthedisintegrationmediumandthetimetodisintegratecompletely was noted. A glass of 80-100 mm long plastic pipe with an inner diameter of approximately 28 mm and an outer diameter of 30-31 mm equipped with a rustproof wire gauge at the bottom. Six tablets were put in the pipe, raising and lowering the tube in such a way that 28 to 32 per minute repeated the full up and down motion. If there are no particles above the gage that pass through the mesh easily, then the tablets disintegrate. The values are shown in table 1.5.

Thickness and Diameter

Vernier calipers were used to evaluate the tablet thicknesses and diameter by using standard operating procedure.

Invitro Drug Release

The drug release testing of the formulated tablet was conducted by using USP paddle apparatus. It was carried out for 08 hrs with 900 ml 1.2 pH buffer acid solution maintained at 37±0.5◦C and agitated at 75 rpm. 5 ml of dissolution medium was with drawn, filtered and diluted at regular intervals to determine the percentage drug release. The drug concentration was determined by calibration curve equation.

Result and Discussion

Preparation Poly herbal formulation

Poly herbal tablet formulations were prepared using the four herbal drug extracts. Formulations containing varying amount of extracts were prepared. Amount of extracts, in any individual formulation was based on marketed preparations of these drugs. Four tablet formulations containing powdered extracts of Carissa carandus,Ocimum sanctum, Moringaolei frea, Manilkara zapota. All the four formulations were evaluated for their hardness, thickness, friability, weight variation, moisture content and in vitro disintegration time.

Evaluation of Herbal Formulation

The results of bulk density, angle of repose, Compressibility Index and Hausner'sratio were indicated that the poly herbal powder mixture possess good flow properties and good packing ability (Table 1.2, Figure 1.1 and 1.2). After a formulation by a direct compression method using automated punching machine, developed poly herbal tablets were subjected to measuring of post compression parameters like uniformity of weight, uniformity of content, hardness, friability, thickness, and disintegration time Of the tablets. All the parameters of the test products are complied with the Pharmacopeial requirements (Table 1.3,Figure1.2).

In the weight variation test the percentage weight variation in all the tablet formulations was within the pharmacopoeial limit. The variation was in range of1.85±0.21 to 2.65±0.31% indicating the maximum percentage variation in F4 and minimum inF1. Thus all the formulations pass the test(Table 1.4, Figure 1.1 and1.2).

The hardness of formulation was measured in kg/cm^{2}withthehelpofMonsantotester. Amongst all the formulations prepared, F1 has been found to be the most acceptable one in terms of weight variation and in vitro disintegration time. This formulation showed appreciable hardness characteristics, which facilitated its fast disintegration. The friability of formulation indicated that the tablets were mechanically stable. As the average weight of tablets was 550 mg, the acceptable weight variation range is ±5%. Hence the entire formulated tablet passed the weight variation test. The disintegration time of formulation was not more than 25 Minutes(Table1.5,Figure1.1. and 1.2).

The tablets require a certain amount of strength or hardness and resistance friability to with stand mechanical shocks of handling in all processes. The hardness of tablets was determined by Monsento hardness tester. The hardness of tablets was in range of 3.1 ±0.02 to 4.1± 0.03 indicating maximum in F3 and minimum in F1. The hardness of tablets was within the Pharmacopoeial limit. Thus all the tablets pass the hardness test.

The friability of tablets was determined by Roche friabilator. The percentage friability was in range of 0.59 ± 0.01 to 0.92 ± 0.01 indicating maximum with F4 and minimumwithF1.Therangeofpercentagefriability was within the pharmacopoeial limit. Thus all the formulations passed the friability test.

The disintegration time of tablets of all the formulations was determined using IP disintegration test apparatus. The time required to disintegrate the tablets was in range of 18.40±1.27to24.15±1.83 min. indicating maximum with F2 and minimum with F1. The range of disintegration time was within the pharmacopoeial limit. Thus all the formulation passed the disintegration test. The formulations F1-F4 were evaluated for in vitro drug release. The formulation F1 was found suitable which gave 100% drug release in 12hrs.

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Table 1.2 Angle of repose, loose bulk density and Tapped bulk density of formulated tablets

S.N.	Batches	Angle of repose(θ)	bulk density(g/ml)	d bulk density(g/ml)
01	F1	22.1±1.04	0.48±0.07	0.45±0.04
02	F2	29.3±1.85	0.54±0.02	0.53±0.07
03	F3	24.5±1.38	0.56±0.04	0.51±0.10
04	F4	27.6±1.94	0.61±0.06	0.49±0.12

Table 1.3 Color, Hausner Ratio and Compressibility index (%) of prepared poly herbal tablet

S. N.	Batches	Color	Hausner Ratio	Compressibility index(%)
01	F1	Grey-Brown	1.32±0.14	15.35±0.85
02	F2	Grey-Brown	1.68±0.20	19.85±1.0
03	F3	Grey-Brown	1.54±0.16	17.50±0.64
04	F4	Grey-Brown	1.95±0.31	16.45±0.82

Table 1.4 Weight variation, Hardness(Kg/cm^2) and Friability(%)test of prepared poly herbal tablet

S. N.	Batch	Wight variation(±5%)	Hardness(Kg/cm^2)	riability(%)
01	F1	1.85± 0.21	3.1 ± 0.02	0.59 ± 0.01
02	F2	2.30±0.18	3.8 ± 0.05	0.89 ± 0.01
03	F3	2.35±0.24	4.1 ± 0.03	0.76 ± 0.03
04	F4	2.65±0.31	3.6 ± 0.04	0.92 ± 0.01

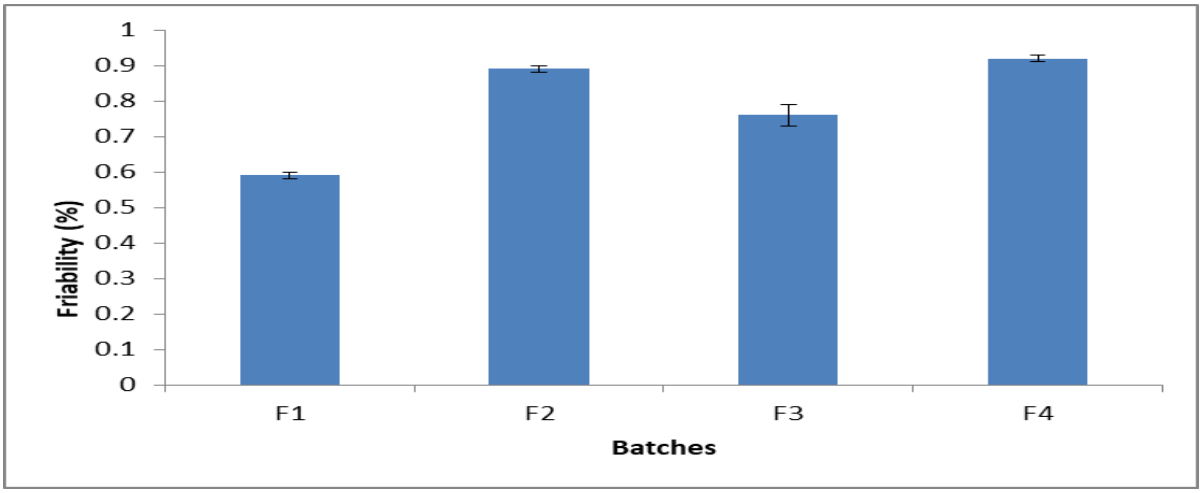

Figure1.1 Friability test of prepared poly herbal tablet

Table1.5Thickness, diameter and disintegration time of formulated tablets

S. N.	Batch	Thickness(mm)	Diameter(mm)	tegration time(min)
01	F1	4.3 ± 0.01	10.1± 0.02	18.40±1.27
02	F2	4.7 ± 0.03	10.8± 0.05	24.15±1.83
03	F3	4.6 ± 0.01	10.5± 0.03	20. 20±1.75
04	F4	3.9 ± 0.02	10.3± 0.01	21.30±1.61

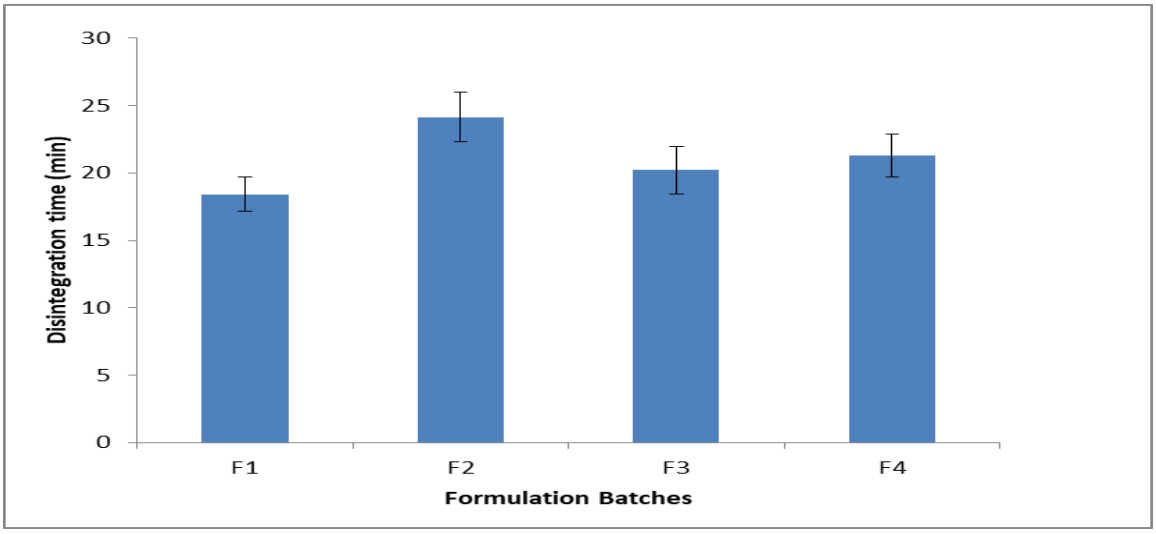

Figure1.2 Disintegration time of prepared poly herbal tablet