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Formulation and evaluation of herbal Antidiabetic tablet of *Cinnamomumtamal*

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Abstract: - Medicinal plants play a very important role within the development of potent therapeutic agents. Nowadays estimate that concerning 80 % of individuals in developing countries still relays on ancient drugs based mostly on species of plants and animals for his or her primary health care. Flavoring medication is use of therapeutic herbs to prevent and treat diseases and ailments or to support health and healing.The World Health Organization (WHO) estimates that 80 % of the population of some Asian and African countries presently use flavored medication for a few side of primary health care. Prescription drugs are prohibitively dearly-won for many of the world's population, half whom lived on less than $2 U.S. per day in 2002.
Key words: Ketoacidosis, Hyperglycaemia, Diabetes mellitus, NDDG

1. Introduction

1.1 General Introduction Of Diabetes

Both World Health Organization and also the NDA Group made new diagnostic criteria and a brand new arrangement for diabetes within the late Nineteen Seventies. This brought order to a chaotic state of affairs during which and diagnostic criteria terminology varied showed monumental variations exploitation totally different oral aldohexose hundreds. World Health Organization slightly modified their criteria to coincide further closely with the NDDG values In 1985. [1]

1.2. Types of Diabetes

The aetiological types designate defects, disorders or processes which often result in DM.

1.2.1. Type 1indicates the method of beta–cell destruction which will ultimately lead to DM during which "insulin is needed for survival" to prevent the event of ketoacidosis, coma and death. Patients with a Type 1 process may be metabolically normal prior to the disease is clinically manifest, although the method of beta–cell destruction will be detected.

1.2.2. Type 2is that the most typical variety of hyperglycemia and is characterized by disorders of endocrine action and endocrine secretion, either of which can be the pre-dominant feature. Each is generally present at the time that this kind of hyperglycemia is clinically manifest. By definition, the particular reasons for the event of thatabnormalitiesare not nevertheless identified.

1.2.3. Other Specific TypesOther specific type are presently less common causes of DM, however are those within which the underlying defect or disease method may be known in an comparatively specific manner. They embrace, for EX., fibro calculouspancreatopathy, a range of hyperglycaemia that was at one time classified one varietyof malnutrition–relatedDM.[2]

1.3 Plant Profile

The bark of varied Cinnamomum species is one amongst the foremost necessary and widespread spices used worldwide not just for cooking however conjointly in ancient and modern medicines. Over-all, some 250 species are known among the Cinnamomum genus, with trees being scattered everywhere the world. [3, 4]

Cinnamomum is especially employed in the aroma and essence industries owing to its fragrance, which may be incorporated into totally different kinds of foodstuffs, perfumes, and healthful product.[5]

2. Material And Methods

2.1. Preparation of extract:

The whole plant of *c. tamala* was collected from the ayurvedicshop. The plant was identified and authenticated by the Dr.S.N.Mishra(Head AINP on M & AP) KNK College of Horticulture. The leaves were washed in tap water and then left to dry at room temperature for 2-3 days. The dried leaves were ground to coarse to fine powder in a mixer and then extracted with 95% ethanol using a soxhlet apparatus for 15 hours. After filtration, the concentrate was dried to yield dried powder. [6]

2.2. Preparation of tablets by wet granulation method

- Starch was weighed and made into an emulsion along with preservatives and cooked well On a water bath until translucent semisolid mass was formed.
- The weighed quantities of excipients were mixed thoroughly with extract, the cooked starch paste were added slowly till the powder became a damp mass.
- This damp mass was passed through sieve number 16 and dried in an oven at a temperature of 50°C, until granules were dried properly.
- Then the dried granules were passed through sieve number 20.
- Finally the tablets were compressed with 12mm punches by using single punch machine.[7]

Formulation

Shows in Table no. 1 and Fig. no. 1, 2, 3

2.3. Evaluation

2.3.1. Pre-compression parameter of blended powder

Angle of repose

A funnel was kept vertically in a stand at a specified height above a paper placed on a horizontal surface. The funnel bottom is closed and powder is filled in funnel. Then funnel was opened to release the powder on the paper to form a smooth conical heap, is found by measuring in different direction. The height of the heap was measured by using scale.

The value of angle of repose is calculated by using the following formula:

$\tan \theta = h/r$

$$\theta = \tan^{-1} h/r$$

Where, h = height of powder cone formed
r = radius of the powder cone formed

Bulk density

Apparent bulk density was determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.

Bulk Density = Weight of the powder / volume of the packing

Tapped bulk density

A known mass of drug excipient blend was placed in a graduated cylinder. The cylinder was tapped on to a hard surface from the height. Tapping was continued, “until no further change in volume was noted”.

Tapped Bulk Density = Weight of the powder / volume of the tapped packing.

Compressibility index

The Compressibility index of the blends was determined by Carr's compressibility index.
Compressibility index (%) = (Tapped Bulk Density- Bulk Density) x 100 / TappedBulk Density

Hausner's ratio
Hausner Ratio was calculated using the formula
Hausner Ratio = Dt / Do
Where;
Dt = tapped density
Do =bulk density

2.4.2. Evaluation of tablets
Weight variation test
By randomly selecting and weighing 20 tablets, the average weight was determined. Individually, each tablet was also weighed. In each case "deviation from the average weight was calculated and expressed as percentage. Not more than two of the tablets from the sample size deviate from the average weight by a greater percentage and none of the tablets deviate by more than double that percentage. [8]
Thickness
Thickness of tablets was determined using vernire caliper. Five tablets from each batch were used, and an average value was calculated.
Hardness
The crushing strength of the tablets was measured using a Monsanto hardness tester. Three tablets from each formulation batch were tested randomly and the average reading noted.
Friability
Ten tablets were weighed and placed in a Roche friabilator and the equipment was rotated at 25 rpm for 4 minutes. The tablets were taken out, deducted, and reweighed. The percentage friability of the tablets was measured as per the following formula. [9]

$$\text{Percentage friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

In Vitro Disintegration Time
The disintegration time of the tablets was determined as per Indian Pharmacopoeial monograph. The time required for disintegration of six tablets from each batch placed in each tube of disintegration test apparatus were measured at 37 ± 0.5ºC using 900 ml of distilled water. The time required to obtain complete disintegration of all the six tablets was noted.[10]
In vitro dissolution test
The in vitro dissolution test of sustained relese tablets of cinnamomum was carried out according to USP 30 by using Tablet Dissolution Tester.
Preparation of phosphate buffer pH 6.8
Phosphate buffer pH 6.8 was prepared according to USP 30.
Method of Preparation of phosphate buffer pH 6.8
Phosphate Buffer pH 6.8, Mixed Dissolve 28.80 g of disodium hydrogen orthophosphate and 11.45 g of potassium dihydrogen orthophosphate in sufficient water to produce 1000 ml.[11]

Procedure of dissolution test
Six tablets were taken and one tablet was placed in each of the six baskets. Dissolution test was carried out according to above mentioned parameters. Sampling was done in the interval of 1 to 12 hr sample was withdrawn in a sampling and 5ml fresh dissolution media was added to maintain the sink conditon. After completion of 12 hr, the dissolved amount of tablets was determined by employing UV absorption at the wavelength of maximum absorbance (λmax) at about 254 nm on filtered portion of solution under test suitably

diluted with the dissolution medium in comparison with reference working standard solution in the same medium using phosphate buffer pH 6.8 as blank solution.
% Of tablets = (Absorbance of sample/Absorbance of standard) x 100 [12]

Method for Average, Standard Deviation and Relative Standard Deviation

The average result, x - , is calculated by summing the individual results and dividing this sum by the number (n) of individual values:

$$x\text{-} = \frac{x1 + x2 + x3 + x4 + \ldots .}{n}$$

The standard deviation is a measure of how precise the average is, that is, how well the individual numbers agree with each other. It is a measure of a type of error called random error - the kind of error people can't control very well. It is calculated as follows:

standard deviation, $S = \sqrt{\frac{(x_1 - x)^2 + (x_2 - x)^2 + (x_3 - x)^2 + ...}{n-1}}$

The relative standard deviation (RSD) is often times more convenient. It is expressed in percent and is obtained by multiplying the standard deviation by 100 and dividing this product by the average.
Relative standard deviation, RSD = 100S/x [13]

3. Result And Discussion

Formulations prepared by wet granulation method were tested for the preformulation studies for potential evaluation to tablet compression. All the evaluated preformulation parameters are shown in table 2. Based on the preformulation studies powder flow properties are good. Then the process is continued with compression of tablet by wet granulation method, after compression tablets were evaluated by Physical parameters observed were displayed on below table3.

Formulations prepared by wet granulation method were tested for the preformulation studies such as angle of repose, bulk density, tapped density, compressibility index, **Hausner's ratio** to know the flow property of material at the time of compression; results are show in table2.

The finished tablets color was Blackish; Weight variation was ± 5%, Hardness, 4.8±0.28 ,4.4±0.40, 4.7±0.25 kg/cm2, Friability 0.12 ±0.25, 0.18±0.06 ,0.15±0.05% . Thickness was measured as 3.2±0.25, 3.8±0.55, 3.4±0.30 mm and Disintegration time 9.3±0.57, 10.6±1.5, 10.3±1.1 min are good for stability to consume for human use.Results are show in table 4.

4. Conclusion

Herbs plays major role in the treatment than the allopathic medicines because of less side effects, low cost and easy availability. The research work done on that basis and the selected plants for the formulation was literally proved for the therapeutic use of anti diabetic purpose.

Plant cinnamomum*tamala* leaves was extracted by using ethanol and the extracts were used to formulate tablets.

Tablet and evaluated for physical parameters and standardize as per pharmacopoeia standards. Preformulation study and Physical Parameter revealed that all the values were within acceptable limit. The herbal formulation showed significant anti diabetic activity and the tablet standardize as per Pharmacopoeia standards.

Based on results it is concluded that the formulation and evaluations are good. Moreover, further study is required for pharmacological evaluation for the treatment of diabetes mellitus.

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Formulation

Table 1: Formulation for herbal anti diabetic tablets.

Ingredients	**BATCH NO.**		
	QUANTITY PER TABLET (mg)		
	F1	F2	F3
Plant extract	200	200	200
Carbopol	50	60	70
Ethyl cellulose	20	15	10
Dibasic calcium Phosphate	30	25	20
Microcrystalline cellulose	80	80	80
Peg 4000	20	20	20
Methyl paraben	0.1	0.1	0.1
Weight per tablet	400	400	400

Table 2: Preformulation parameters for herbal anti diabetic tablets

S.NO.	Parameter	Tablets		
		F1	F2	F3
	Angle of repose	32.85	31.85	30.76
	Bulk density	0.47gm/cm^3	0.45gm/cm^3	0.45gm/cm^3
	Tapped bulk density	0.52gm/cm^3	0.51 gm/cm^3	0.50 gm/cm^3
	Compressibility index	10.6%	13.3%	11.1 %
5.	**Hausner's ratio**	1.10	1.1	1.11

Formulations prepared by wet granulation method were tested for the preformulation studies such as angle of repose, bulk density, tapped density, compressibility index, **Hausner's ratio** to know the flow property of material at the time of compression, results are show in table.

Table 3: Physical parameters for herbal anti diabetic tablets

S.NO.	Parameter	Tablets		
		F1	F2	F3
	Color	Blackish	BlackishBlackish	
	Weight variation test	398.15±1.7	395.2 ±5.5	396 ±4.5
	Hardness(kg/cm2)	4.7±0.28	4.4±0.40	4.8±0.25
	Friability (%)	0.12 ±0.25	0.18±0.06	0.15±0.05
	Thickness(mm)	3.2±0.25	3.8±0.55	3.4±0.30
	Disintegration(min)	9.3±0.57	10.6±1.5	10.3±1.1

The finished tablets color was Blackish; Weight variation was ± 5%, Hardness, 4.8±0.28 ,4.4±0.40, 4.7±0.25 kg/cm2, Friability 0.12 ±0.25, 0.18±0.06 ,0.15±0.05% . Thickness was measured as 3.2±0.25, 3.8±0.55, 3.4±0.30 mm and Disintegration time 9.3±0.57, 10.6±1.5,10.3±1.1 min are good for stability to consume for human use.

Table 4: Calibration of standard curve**:**

S.NO.	Concentration	Absorbance
1	4	0.137
2	8	0.309
3	12	0.356
4	16	0.485
5	20	0.636
6	24	0.772
7	28	0.869
8	32	0.984
9	36	1.086
10	40	1.264

Table 5: Cumulative % drug release of different batches.

Time (h)	Cumulative % drug release of different batches		
	F1	**F2**	**F3**
0	0	0	0
1	0.81	0.82	0.86
2	1.74	1.75	1.84
3	5.5	5.54	6.45
4	11.53	14.57	16.58
5	26.87	27.21	38.14
6	38.52	38.64	49.34
7	41.25	42.13	55.11
8	55.34	57.15	69.84
9	68.46	69.44	74.74
10	74.51	75.14	78.63
11	79.97	80.13	82.45
12	83.51	85.17	86.14

F1-F3 batches are evaluated for dissolution or cumulative % drug release at maintained sink condition temperature, pH and volume of fluid, ionic balance.

Stability study of optimized formulation (F3)

Table 6: Physical parameters for herbal anti diabetic tablets after 1 month

S.N.	Parameter	F3 formulation
1.	**Color**	Blackish
2.	**Weight variation test**	394.1±5.47
3.	**Hardness(kg/cm2)**	4.6 ±0.25
4.	**Friability (%)**	0.19±0.06
5.	**Thickness(mm)**	3.4±0.37
6.	**Disintegration(min)**	9.6±0.57

The finished tablets color was Blackish; Weight variation was ± 5%, Hardness, 4.6±0.25 kg/cm2, Friability 0.19±0.06%. Thickness was measured as 33.4±0.37mm and Disintegration time 9.6±0.57min are good for stability to consume for human use.

Table 7: Cumulative % drug release after 1 month

S.NO.	Time (h)	Absorbance
1	0	0
2	1	0.85
3	2	1.85
4	3	7.43
5	4	16.56
6	5	38.13
7	6	50.3
8	7	55.11
9	8	68.85
10	9	73.74
11	10	77.63
12	11	81.45
13	12	84.14

Formulation

Fig 1-Formulation 1**Fig 2**-Formulation 2**Fig 3**-Formulation 3

Calibration of standard curve in simulated intestinal fluid pH 6.8

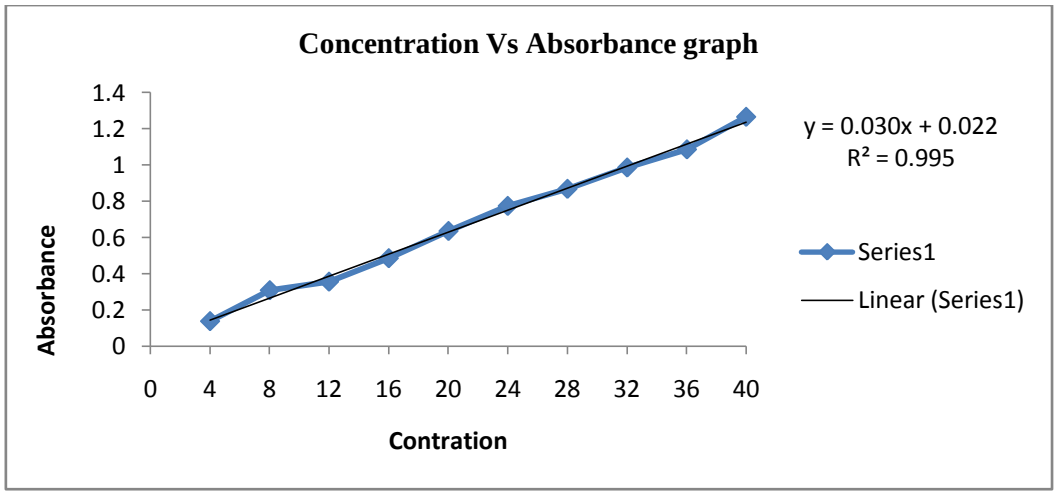

Fig 3: Standard curve

Cumulative % drug release of different batches (F1-F3)

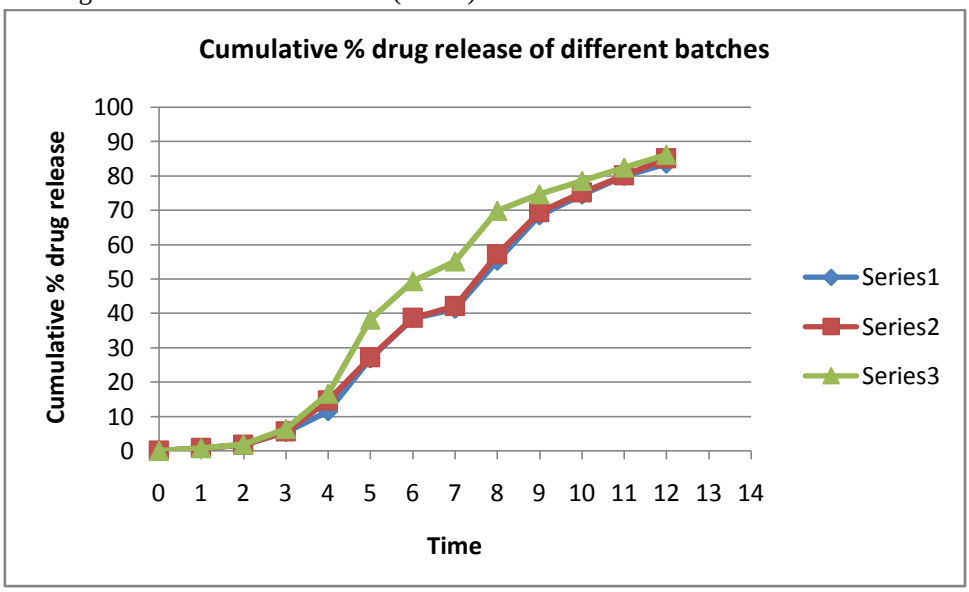

Fig 4: Comparison of cumulative % drug release of different batch

Cumulative % drug release after 1 month (F3)

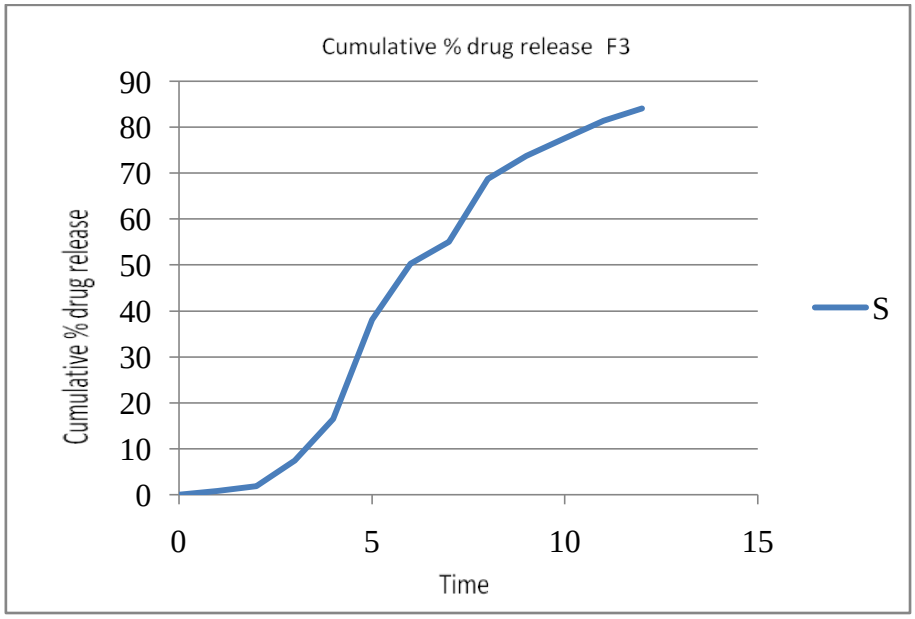

Fig 5: Cumulative % drug release of F3 formulation after 1 month

Table and figure titles and legends:

Table 1: Formulation for herbal anti diabetic tablets.
Table 2: Preformulation parameters for herbal anti diabetic tablets.
Table 3: Physical parameters for herbal anti diabetic tablets.
Table 4: Calibration of standard curve.
Table 5: Cumulative % drug release of different batches.
Table 6: Physical parameters for herbal anti diabetic tablets after 1 month.
Table 7: Cumulative % drug release after 1 month.
Fig 1- Formulation 1
Fig 2- Formulation 2

Fig 3- Formulation 3
Fig 3: Standard curve
Fig 4: Comparison of cumulative % drug release of different batch
Fig 5: Cumulative % drug release of F3 formulation after 1 month