FORMULATION AND EVALUATION OF CAPSULES CONTAINING HERBAL EXTRACTS OF *MUSA PARADISIACA* FOR TREATMENT OF ANAEMIA

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Abstract:
This research focused on the formulation and evaluation of capsules containing herbal extract of *Musa Paradisiaca* for treatment of anaemia. The extract of Musa Paradisiaca was formulated as granules by wet Granulation method using various excipient viz .corn starch, stearic acid, talc, microcrystalline cellulose The granules were designed by using corn starch microcrystalline cellulose as a diluents , disintegrant and binder.stearic acid as a lubricant and talc as a glident . furthermore, the capsules are evaluated for tap density, bulk density, carr's index , hausner's ratio ,angle of repose ,weight variation ,disintegration test ,dissolution test etc. The prepared formulations were subjected to in-vitro dissolution studies and studied for variables affecting the dissolution profile of the capsules. Drug release from F2 and F4 was 85.26 and 83.96 at 12 hrs. From results it was concluded that, for drugs having high dose the Cellulose was better polymer to sustain a drug release and to minimize a drug concentration.

Keywords: musa paradisca extract, capsules , anaemia

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1.Introduction:

Anaemia, defined as a decreased haemoglobin concentration. Given its effects on physical and psychological growth, behaviour, and job performance, iron deficiency anaemia is a severe public health issue.It is the most prevalent nutritional problem in the world today, affecting more than 700 million persons[1]. The most frequent nutritional cause of anaemia, iron deficiency, may also be linked to a folate shortage, especially during pregnancy. Due to their rarity, other nutrient deficits such those in vitamin B, pyridoxine, and copper have little impact on public health. Infants, preschool children, adolescents and women of childbearing age, particularly pregnant women, are at greatest risk of developing iron deficiency anaemia[2]. The consequences of iron deficiency, and especially iron deficiency anaemia, are many. They include as In infants and children[3, 6] : as Impaired motor development and coordination Impaired language development and scholastic achievement ; Psychological and behavioural effects (inattention, fatigue, insecurity,) Decreased physical activity. In adults of both sexes[7,8] weight: Decreased physical work and earning capacity ; Decreased resistance to fatigue. In pregnant women[9,12]: Increased maternal morbidity and mortality ; Increased fetal morbidity and mortality ; Increase risk of low birth weight.

1.1 Clinical Features[13] :

Chronic and frequently asymptomatic, iron-deficiency anaemia can be misdiagnosed for a very long time. Non-specific symptoms including weakness, exhaustion, trouble focusing, and poor work output are attributed to reduced oxygen transport to body tissues and low iron-containing enzyme activity. Common signs and symptoms of IDA are:

- Difficulties with memory and concentration (cognitive)
- Low energy, sluggishness, and fatigue; a slight feeling of lightheadedness or unusual coldness (cardiovascular);Feeling mildly light-headed,
- Mild shortness of breath with exertion that goes away with rest (cardiopulmonary) ; Pale conjunctiva, mucosa, or skin.

1.2 Causes[14 , 15] :

Iron deficiency Anaemia	**Shortage of iron, heavy menstrual bleebleeding**
Vitamin deficiency anaemia	Shortage of folate and vit B- 12
Anaemia of chronic disease	Cancer, HIV/AIDS, Kidney disease
Aplastic anaemia	Infections, certain medicines
Anaemia associated with bone marrow disease	Leukemia, myelofibrosis
Hemolytic anaemia	Red blood cell destruction
Sickle cell anaemia	Red blood cells to assume an abnormal crescent (sickle) shape
Other anaemia	Thalassemia and malarial anaemia

1.3 The capsule dosage form :

The Latin term "capsula," which denotes a little box or container, is where the English word "capsule" first appeared. A solid oral dose form that consists of a container, typically made of gelatin, filled with a medication has been referred to as a capsule in more modern times. The terms "hard" and "soft" are currently used in English to designate two major kinds of capsules that come in a variety of shapes and sizes. The "hard capsule" is made up of two distinct pieces, each of which is shaped like a semi-closed cylinder. The "body" is longer and has a slightly bigger diameter than the other component, the "cap". To create a sealed unit, the cap is tightly secured over the body.

1.4.Capsules offer many advantages[16] :

Capsules, because of their elongated shape, are easy to swallow, which is one reason for the number of capsule – shaped tablets manufacturated today. Flexibility of formulation is another advantage of the capsule dosage form. However the biggest formulation advantage of capsules is that there is less need for additional excipients. Since capsules have no taste, they are good at covering up any unsavoury flavours or odours in their contents. Due to the capsules' quick disintegration, they have properties that allow for rapid release. Hard capsules are also frequently used in clinical trials since the filling of tablets or even the capsules themselves will mask the dosage forms under investigation.

1.5.Musa Paradisiaca :

Musa paradiscal is commonly known as banana flower. Musaceae is the name of the family to which banana flowers belong. Banana blossoms are an important source of the vitamins B-12 and iron.The objective of present study was the utilization of Musa Paradisiaca syndrome could provide health benefits of human being. Bananas can be used for both traditional medicine and

nutrition.The fibers of Musa Paradisiaca contain high iron content and help in the production of red blood cells. The body's haemoglobin levels are raised by these red blood cells. According to Ayurveda, eating a cup of cooked musa Paradisiaca with yoghurt can increase progesterone levels in the body and prevent excessive menstrual bleeding. Banana flowers are also believed to help women suffering from polycystic ovarian syndrome[17].

2.Material and Method :

2.1.Material : Plant materials Samples of musa Paradisiaca of were collected from the banana plantation areas located. The samples were washed under running water to wash away any surface-attached solids. The samples were then sliced and dehydrated at temperature between 40 - 45°C for one week using an oven. The dried samples were ground into fine powder using a grinder.

2.2.Chemicals : Ethanol, stearic acid, corn starch, cmc, colloidal silicon dioxide, drug extract.

2.3.Method of extraction :

Musa Paradisca are harvested. They are washed and sorted. The flowers bracts are removed.The fresh bright flowers were grinded extensively. About 100g of each sample was taken in the 250 ml of the conical flask. Then these samples were extracted overnight with the solvent mixture of 100 ml of ethanol and chloroform in the ratio of 75:25 respectively at room temperature by soxhlet apparatus. The extract from each flask was filtered with Whatman No 1 filter paper. The solvent from extract was evaporated at 500 C leaving behind crude extract only. The crude extract of each sample was stored at 40C until use[19].

2.4.Phytochemical screening of the extract :

The samples extracts were screened for the presence of bioactive compounds such as alkaloids, steroids, terpenoids, saponin, flavanoids, tannin and glycosides [20].The results of the phytochemical study were given in table .

2.5.Granulation[21] :

Granulation is particle agglomeration process that is one of the most important unit operation in preparation of dosage form, namely tablet and capsules . By using dry granulation process, granules for capsule formulation were prepared from given formulation table. The powder mixture is compressed without use of heat .

2.6.Procedure for granulation :

Milling of drug and excipients : The extract and excipients are milled in wet granulation process to produce uniformity in powder and excipients.

Mixing of milled granules: Most important step in granulation is mixing the drug excipients. After milling extract of musa paradisca and excipients, milled drug and excipients are properly combined to prevent blend uniformity and segregation.

Compression into large, to make slug : To produce slug, mixture is squeezed into huge , mixed. These slugs are then ground into granules (de- slugging) . Because fine powder is turned into granules, these phase is essential .

Mixing with lubricant and disintegrating agent: The granules are combined with lubricant and disintegrating agent after de-slugging**.**

2.6.2 Formulation of Capsule

Table. 2.6.2 Formulation of Antianaemic capsules (350 mg per capsules)

Batch	Ingredients				
	Extract of musa Paradisiaca	**Corn starch**	**Stearic acid**	**Colloidal silicon dioxide**	**MCC**
F1	200	10.5	3.5	1	135
F2	200	35	3.5	1	110.5
F3	200	87.5	3.5	1	58
F4	200	10.5	7	1	131.5
F5	200	35	7	1	107
F6	200	65.5	5	1	78.5
F7	200	87.5	7.5	1	54
F8	200	65.5	3.5	1	80

2.2 Evaluation test [22, 28]

2.2.1.Pre-Compression parameters:

2.1.1.Bulk and Tapped density :

Both those bulk density and tapped density were determined. Powder from each formulation, previously lightly shaken to break any agglomerates formed was introduced into a 10ml measuring cylinder. After the initial volume was observed, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5cm at 2 sec intervals. The tapping was continued until there was no further change in volume. Bulk density is calculated by using a formula:

Bulk density = Weight of sample in gm /volume occupied by sample in ml

The final volume was measured, and the tap density was computed using the equation below:
Tapped density= Weight of sample in gm /volume occupied by sample in ml

2.1.2.Carr's index and Hausner's Ratio :
A simple test for evaluating powder friability has been created, which includes the poured (fluff) density and tapped density of a powder, as well as the pace at which it packed down. Carr's index provides a valuable empirical guidance.
Compressibility index = Bulk density − Tapped density

2.1.3.Hausner's Ratio :
Hausner found that the ratio tapped density /bulk density was related to inter particle friction as such, could be used to predict powder flow properties.
Hausner′ sratio = Bulk density /Tapped density

2.1.4.Angle of repose:
Angle of repose is used to measure flow properties. Improper flow of powder is due to frictional forces are qualified by angle of repose. Angle of repose was determined by substituting the values of the base radius 'r' and height of the pile 'h' in the given equation given below,
Tan θ = h/r
Where, θ = Angle of repose,
h = Height of pile,
r = Radius of base

2.3.1.Post-compression parameters :
All prepared granules were tested for the official and unofficial parameters listed below.

3.1.1 Appearance:
The granules were identified by checking the difference in colour.

3.1.2.Weight variation:
Twenty capsules were randomly selected from and weighed individually to check for weight variation. According to USP, the following % deviation in weight fluctuation was permitted. In all formulations, the capsule weight was 350 mg , hence a maximum deviation of +10% from the average capsule weight was allowed.

3.1.3.Drug content :
Weighing an amount of granules equivalent to 50 mg of losartan potassium, it was dissolved in 100 ml of phosphate buffer pH 6.8, filtered, diluted appropriately, and analysed for drug content at 275 nm with a UV-visible spectrophotometer.

3.1.4.In-vitro Drug Release Study :
The release rate of banana flower from granules was determined using IP Dissolution Test Apparatus Type II (basket type). At the start of each test, granules were placed in an empty hard gelatin capsule of size #0 and then placed in a dry basket. Lower the basket in the dissolution medium and apparatus was run at 50 rpm, The dissolution test was performed using 900 ml of phosphate buffer pH 6.8, at 37±0.5ºC and 50 rpm. For 60 minutes, 5 mL were removed at five-minute intervals. This was kept at the same temperature and added to the mass. The samples were filtered using No. 41 Whatman filter paper. The samples were filtered through Whatman filter paper no. 41. Absorbance of these solutions was measured at 275 nm using UV-Visible spectrophotometer. A standard curve calculation was used to compute the cumulative percentage medication release.

3.Result and Discussion :
3.1 Preformulation studies of Musa Paradisca
3.1.1 Morphology:
Table. 3.1.1 Physical characterization of musa Paradisiaca :

Sr. No	Physical properties	Observation
1.	Appearance	Bright red to brown
2.	Color	Brown red
3.	Odor	Characteristics
4.	Taste	Pleasent
5.	Melting point	118^0C

3.1.2.Solubility :
Table. 3.1.2.Solubility tests of musa Paradisiaca in various solvents :

Sr. No	Solvents	Solvents behavior
1.	Acetone	Partially soluble
2.	Ethanol	Freely soluble
3.	Chloroform	Soluble
4.	Water	Insoluble

3.1.3.FT-IR Spectrum of Musa Paradisca:
FT-IR Spectra of Musa Paradisca and F2 formulation were recorded. All these peaks have appeared in formulation and physical mixture, indicating no chemical interaction between blossom and polymer.

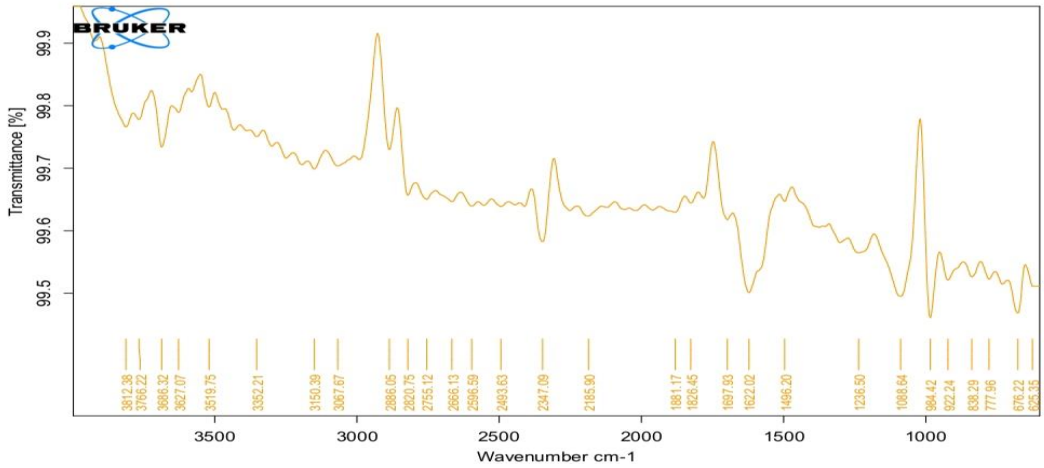

Fig. 3.1.3.FT-IR Spectrum of Musa paradisca

3.2.Phytochemical screening of the extract :

Alkaloid	**Present**
Glycoside	Present
Flavonoid	Present
Saponin	Present
Tannin	Present
Terpenoids	Present

The selected herbal drug has shown the presence of all chief chemical constituent as per earlier studies. Thus, it has been certified the authenticity of herbal drug .

3.2.Pre-Compression study :

Table.3.2.1.Flow properties

Batch	Angle of repose (g/ml)	Bulk Density(g/ml	Tapped density(n=3)	Carr's index(n=3)	Hausner's ratio
F1	23.48±0.58	0.265±0.04	0.425±0.07	14.07±1.01	1.16±0.012
F2	24.32±0.32	0.298±0.012	0.437±0.012	15.95±0.74	1.19±0.012
F3	26.22±0.12	0.342±0.004	0.413±0.004	14.75±0.73	1.18±0.011
F4	24.40±0.42	0.298±0.04	0.437±0.04	15.95±0.96	1.19±0.014
F5	22.85±0.22	0.321±0.07	0.428±0.04	15.61±1.28	1.1218±0.012
F6	34.34±0.34	0.298±0.03	0.437±0.04	15.95±0.76	1.19±0.013
F7	26.68±0.12	0.348±0.04	0.418±0.04	15.75±0.73	1.16±0.011
F8	28.92±0.81	0.348±0.03	0.428±0.05	15.75±0.73	1.16±0.011

Table.3.2.2: Quality Control Parameters of capsules :

Formulation No	Average weight (mean±S D) (n=20)	Drug Content (%)	Disintegration time (min) (IP Specification NMT 30 min)
F1	360±0.6	86.10	10
F2	320±0.9	85.20	11
F3	340±0.3	88.55	10
F4	350±0.4	77.50	9
F5	300±0.8	76.58	10
F6	310±0.8	75.34	11
F7	300±0.4	87.50	10
F8	330±0.4	71.58	11

Table.3.2.3 : Dissolution Data of capsules in different concentrations

Time (Hr)	Cumulative percentage drug dissolved (n=3±S.D)							
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**
0	0	0	0	0	0	0	0	0
2	25.36	26.39	25.98	24.59	26.79	23.40	24.80	23.85
4	35.26	36.29	37.59	39.65	34.56	32.71	33.10	32.71
6	50.26	49.67	50.26	49.99	48.26	48.56	46.29	47.36
8	62.35	59.66	61.29	64.26	63.54	65.30	59.80	60.55
10	77.26	79.98	79.29	73.29	72.59	72.28	70.60	73.60
12	79.36	85.26	82.29	83.96	83.85	82.10	81.90	82.26

The prepared formulations were subjected to in-vitro dissolution studies and studied for variables affecting the dissolution profile of the capsules. From results it was concluded that, for drugs having high dose the Cellulose was better polymer to sustain a drug release and to minimize a drug concentration. Drug release from F2 and F4 was 85.26 and 83.96 at 12 hrs.

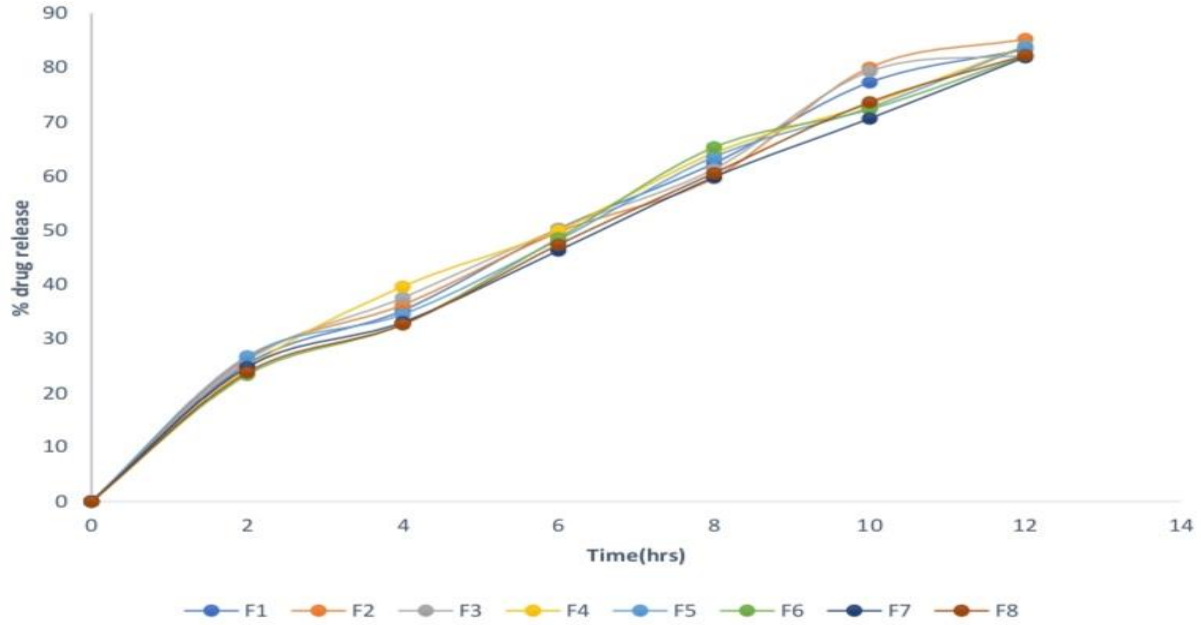

Fig. 3.2.3.Percentage drug release of formulations(F1-F7)

4. Summary:

Musa Paradisca contain blossom biologically active compounds which have significant antianemic activity. Musa Paradisiaca shows antianemic activity and can be used in adults to treat anemia. musa paradisca antianemic capsules was found suitable as sustained release capsule and were found suitable for oral sustained release products. Musa paradisca is reported as non-toxic. High availability and low cost of food-based nutraceuticals have been a significant advantage to its users. Thus, capsule containing extract of Musa paradisca are found to be good alternative to treat anemia.

5. Conclusion:

The aim of this study was to formulate and evaluate musa paradisca anemic capsules for treatment of anemia. Preformulation studies on musa paradisca performed in accordance with the reported literature limits. The drug content of capsules were uniform and reproducible. In vitro dissolution profile of musa paradisca formulation showing promising results. Dissolution studies results indicated that the musa paradisca capsules was not generally similar and constant for all formulations containing different control releasing materials. Overall decrease in musa paradisca release rate with respective decrease in the ratio of polymer in formulations. These polymers showed constant & sustained release rate up to 12 hrs.

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