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FORMULATION AND EVALUATION OF MORINGA EXTRACT TABLETS FOR NUTRITIONAL SUPPLEMENT

I. Mamatha[1], Chenna.Rajeshwari[2], Chevula.Anusha[2], Jangam.kedarinath[2], Sydupally. Sruthi[2]

[1] Associate professor, Department of pharmaceutical chemistry Joginpally B.R Pharmacy College, Yenkapally(V), Moinabad(M), R.R District, Hyderabad, Telangana-500075 India.
[2] Students, Department of Pharmaceutics, Joginpally B.R Pharmacy College, Yenkapally(V), Moinabad(M), R.R District, Hyderabad, Telangana-500075 India.

Abstract:
The present study was aimed at the formulation and evaluation of Moringa extract tablets as a nutritional supplement. Moringa leaves were dried, powdered, and extracted using suitable solvent extraction method. The obtained extract was formulated into tablets by direct compression technique using excipients such as microcrystalline cellulose, sodium starch glycolate, talc, magnesium stearate, and aspartame. Different formulations (F1–F4) were prepared and evaluated for pre-compression parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. The formulated tablets were further evaluated for post-compression parameters such as weight variation, hardness, thickness, friability, disintegration time, drug content, and dissolution studies. Among all formulations, formulation F2 showed satisfactory physicochemical characteristics with acceptable hardness, low friability, uniform weight variation, and rapid disintegration time. Dissolution studies revealed that formulation F2 exhibited better drug release profile compared to other formulations, showing maximum release within the specified time period. The results indicated that F2 was the optimized formulation and the developed Moringa extract tablets can be effectively used as a nutritional supplement with improved patient compliance and acceptable tablet characteristics.

Keywords: *Moringa Extract, FTIR Studies, Direct compression technique, In vitro drug release studies.*

Corresponding author:
I. Mamatha,
Associate professor, Department of pharmaceutical chemistry,
Joginpally B.R Pharmacy College, Hyderabad, Telangana - 500075, India.
Mobile:
Email Id:

QR CODE

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INTRODUCTION:

The use of plants as medicine goes back to the period of early humans. Fossil records human use of plants as medicines at least to the Middle Paleolithic age. Evidences of this early association have been found in the grave of a Neanderthal man buried 60,000 years ago. The earliest known medical document is a 4000-year-old Sumerian clay tablet that recorded plant remedies for various illnesses. By the time of the ancient Egyptian civilization, a great wealth of information already existed on medicinal plants. This information, along with the hundreds of other remedies, has been preserved in the Ebers papyrus for nearly 3500 years. The development of systematic pharmacopoeias dates back to 3000 BC, when the Chinese were already using more than 350 herbal remedies. China has demonstrated the best use of traditional medicine in providing health care. Ayurveda, a system of herbal medicines widely practiced in India, Sri Lanka, and Southeast Asia has more than 8000 plant remedies and uses nearly 35,000 to 70,000 plant species. Among the ancient civilizations, India have been known to be the richest repository of medicinal plants. About 8000 herbal remedies have been codified in Ayurveda. The Rigveda (5000 BC) has recorded 67 medicinal plants, the Yajurveda 81 species, the Atharvaveda (4500-2500 BC) 290 species, and the Charak Samhita (700 BC) and Sushrut Samhita (200 BC) have described properties and uses of 1100 and 1270 species, respectively, to compound the drugs and use. It is a well-known fact that Traditional Systems of medicines always played important role in meeting the global health care needs. They are continuing to do so at present and shall play major role in future also. The system of medicines which are considered to be Indian in origin or the systems of medicine, which have come to India from outside and got assimilated in to Indian culture are known as Indian Systems of Medicine. India has the unique distinction of having six recognized systems of medicine in this category. They are: Ayurveda, Siddha, Unani and Yoga, Naturopathy and Homoeopathy.

Current Status of Herbal Medicine

Currently more than 80% of the world population depends on traditional and plant derived medicine because, plants are important sources of medicines and presently about 25% of pharmaceutical prescriptions in the United States contain at least one plant-derived ingredient. In the last century, roughly 121 pharmaceutical products were formulated based on the traditional knowledge obtained from various sources.

Future importance of Herbal Medicine

It is estimated that there are about 350,000 species of existing plants (including seed plants, bryophytes, and ferns), among which 287,655 species have been identified as of 2004. Relatively small percentages (1 to 10%) of these are used as foods by both humans and other animal species. It is possible that even more are used for medicinal purpose

MATERIALS:

Moringa extract was procured from Synpharma Research Labs, Hyd, Sodium starch glycolate, Magnesium stearate, Aspartame ,Talc and Micro crystalline cellulose were obtained from Synpharma Research Labs, Hyderabad. Other chemicals and the reagents used were of analytical grade.

METHODOLOGY:

Drug excipient compatibility

Compatibility studies of Moringa extract and the disintegrants were carried out by using Fourier Transform Infrared Spectroscopy (FTIR). Fourier transform infrared spectra of the samples were obtained in the range of 4000 to 450 cm-1 using a FTIR by the KBr disc method.

Preparation of M. oleifera leaf for extraction

The fresh leaves were cleaned out first with tape water to remove dusts and dirt then washed with distilled water twice. The cleaned leaves were dried in oven at 45 C for 3 to 5 days to get a constant weight dry mass. The dry leaves then powdered using grinding mill to a particle size of about 0.5 mm. The powdered dried leaves then packed in polyethylene bag and stored in sealed container at dark cool room until use.

Extraction of dried powdered M. oleifera leaf:

About 50 g of dried powdered Moringa leaf is accurately weighed and packed in a thimble made of filter paper.The dried powdered is placed inside the Soxhlet extractor.Approximately 300–400 mL of ethanol solvent is poured into the round bottom flask.The Soxhlet apparatus is assembled with condenser and heated using a heating mantle.Extraction is continued for about 6–8 hours until the solvent in siphon tube becomes colorless.After completion of extraction, the extract is filtered and concentrated using rotary evaporator or water bath at temperature below 50°C.The concentrated extract is dried to obtain semisolid or dry extract.The dried extract is stored in an airtight container for further formulation studies.

Percentage Yield= Weight of Extract Obtained / Weight of Powder Taken ×100

Table-1: Formulation Table of Moringa extract Tablets

S.NO.	INGREDIENTS (mg)	F1	F 2	F 3	F 4
1	Moringa extract	50	50	50	50
2	Sodium starch glycolate	25	50	75	100
4	Microcrystalline Cellulose	160	135	110	85
5	Magnesium stearate	3	3	3	3
6	Talc	2	2	2	2
7	Aspartame	10	10	10	10
8	Total Wt.	250	250	250	250

Direct compression technique

Moringa extract tablets of were prepared by direct compression. All the ingredients were passed through 40-mesh separately. Then the ingredients were weighed and mixed in geometrical order and compressed into tablets of 250 mg using 8mm round flat punches on 8-station rotary tablet machine (Rimek).

Evaluation studies

1.Pre-compression parameters

a) Bulk Density

Bulk density is defined as the mass of powder divided by bulk volume.

It is calculated using the following equation:

Bulk density = weight of sample taken /volume noted

An accurately weighed quantity of the powder (W) was carefully poured into the graduated cylinder and the volume (vo) was measured. Then the cylinder was dropped at 2-second intervals onto a hard-wooden surface three times, from a height of one inch. The volume was recorded and the bulk density was calculated.

b) Tap density

An accurately weighed quantity of the powder (W) was carefully poured into the graduated cylinder and the volume (vo) was measured. Then the surface was carefully smoothed and the volume was measured. Tap density was calculated by measuring final volume (Vf) after 50 taps on wooden surface from 6 inch height and was expressed in g/cm3 .

Bulk density = W/Vo

Tapped density = W/Vf

Where,

Vo = initial volume

Vf = final volume.

Compressibility index and Hauners ratio

The Compressibility index and Hauners ratio are measures of the propensity of a powder to be compressed. As such, they are measures of the relative importance of inter particulate interactions. In a free-flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater inter particle interactions and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the compressibility index and Hausner ratio.

Angle of repose

The flow characteristics are measured by angle of repose. Improper flow of powder is due to frictional forces between the particles. These frictional forces are quantified by angle of repose.

Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and the horizontal plane.

$\tan\theta = h/r$

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

Where

h = height of pile

r = radius of the base of the pile

θ = angle of repose

Post compression parameters

Weight variation:

Method:

Twenty tablets were randomly selected form each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more then two of the individual tablet weight deviate from the average weight by more than the percentage shown in Table No 1 and none deviate by more than twice the percentage shown.

Table-2: Percentage deviation allowed under weight variation

Percentage deviation allowed under weight variation test.	
Average weight of tablet (X mg)	Percentage deviation
130 mg or less 130mg to 324 mg more than 324 mg	10 7.5 5

Thickness:
Twenty tablets were randomly selected form each batch and there thickness was measured by using vernier caliper. Thickness of three tablets from each batch was measured and mean was calculated.

Hardness:
Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm2. Three tablets were randomly picked and hardness of the tablets were determined.

Friability:
Friability test is performed to assess the effect of friction and shocks, which may often cause tablet to chip, cap or break. Roche friabilator was used for the purpose. This device subjects a number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at distance of 6 inches with each revolution. Twenty tablets were weighed and placed in the Roche friabilator, which was then operated for 25 rpm for 4 min. After revolution Tablets were dedusted and reweighed. Compressed tablets should not loose more than 1% of their weight.
The percentage friability was measured using the formula,

$$\% F = \{1-(Wo/W)\} \times 100$$

Where,
% F = friability in percentage
Wo = Initial weight of tablet
W = weight of tablets after revolution

Disintegration time:
The disintegration time of tablets was determined by using Disintegration test apparatus (scientific). Tablets were placed in disintegration test assembly and disc was placed on tablets in each glass tube of assembly. The assembly was dipped in a vessel containing 900 ml distilled water at 37°C. The time for disappearance of tablet residue above mesh was noted as disintegration time.

In- Vitro Release study:
In-Vitro drug release studies were carried out using Tablet dissolution test apparatus USP II at 100 rpm. The dissolution medium consisted of 900 ml of Standard buffer pH 6.8 . Temperature maintained at 37±5.The sample of 5ml was withdrawn at predetermined time intervals and an equivalent amount of fresh dissolution fluid equilibrated at the same temperature was replaced. From that 5 ml sample, 1 ml sample was withdrawn and placed in a 10 ml volumetric flask and make the volume with distilled water. The diluted samples were assayed at 280 nm against reagent blank.

Stability studies:
The success of an effective formulation can be evaluated only through stability studies. The purpose of stability testing is to obtain a stable product which assures its safety and efficacy up to the end of shelf life at defined storage conditions and peak profile. The prepared Matrix tablets of Moringa extract were placed on plastic tubes containing desiccant and stored at ambient conditions, such as at room temperature, 40±2oc and refrigerator 2-8oc for a period of 90 days.

RESULTS AND DISCUSSION:

Drug - excipient compatibility studies (FT-IR)
The compatibility between the drug and the selected Moringa oleifera and other excipients was evaluated using FTIR peak matching method. There was no appearance or disappearance of peaks in the drug-excipients mixture, which confirmed the absence of any chemical interaction between the drug, polymers and other chemicals.

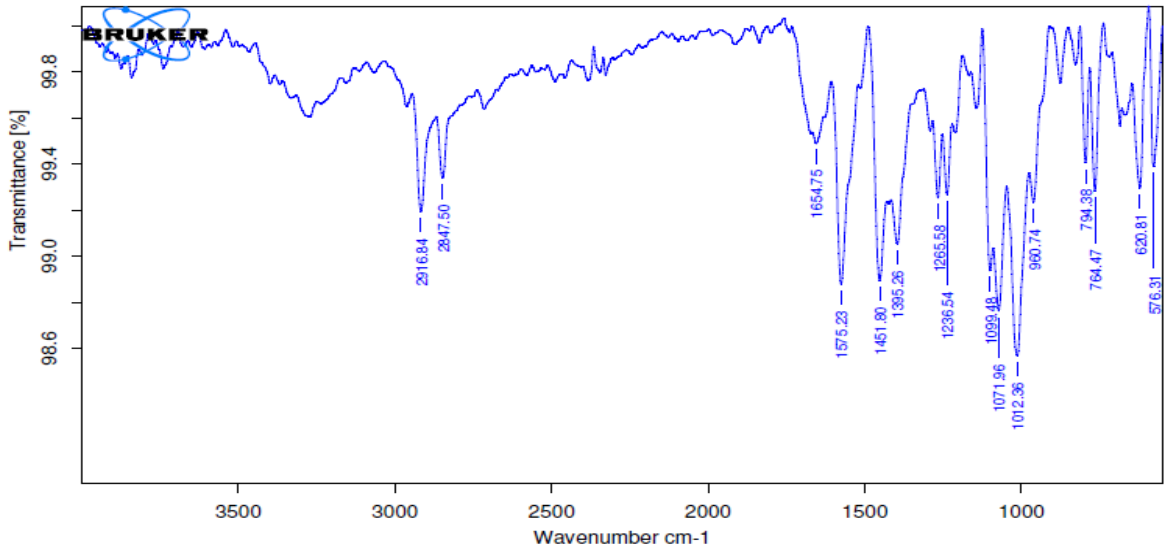


Fig-:1 FTIR Studies of Moringa oleifera

Table-: 3 Characteristic Peaks for Moringa oleifera

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3000-2500	2916.84 cm-1
2	OH Bending	2000-1500	1575.23 cm-1
3	C=O stretching	1500-1000	1451.80 cm-1

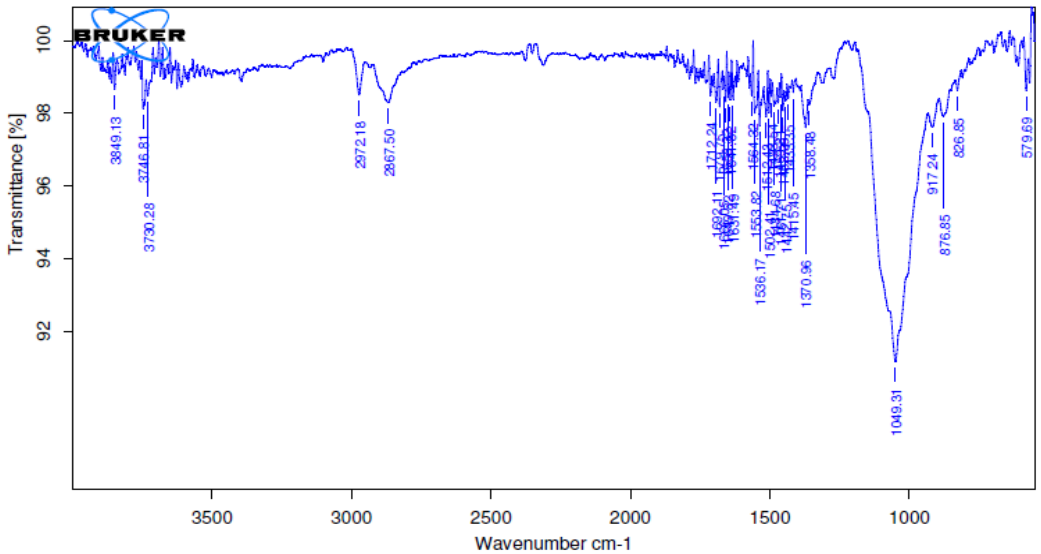


Fig-:2 FTIR Studies of Optimized formulation

Table-:4 Characteristic Peaks for Optimized formulation

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3500-3000	2972.18
2	OH Bending	1000-1500	1049.31
3	C-H stretching	3000-2500	2867.50
4	C=O stretching	2000-1500	1692.11

EVALUATION STUDIES

Pre compression Parameters

Bulk Density: The bulk density for the formulated blend was carried out for all formulation and found in the range of 0.569-0.574.

Tapped density: The tapped density for the formulated blend was carried out for all formulation and found in the range of 0.612-0.620.

Angle of repose: The angle of repose for the formulated blend was carried out and the results were shown in Table. It concludes that all the formulations blend was found to be in the range of 26^0 to 30^0

Compressibility index: Compressibility index was carried out, it found between 10% to 14.27 % indicating the powder blend have the required flow property for compression.

Hauser ratio: Hauser ratio was carried out, it found between 1.17 to 1.21 indicating the powder blend have the required flow property for compression.

Table-5: Results of Pre-compression parameters of Blend

F. No	Bulk density	Tapped density	Compressibility index	Hauser ratio	Angle of repose (0)
F1	0.569	0.612	13.24	1.17	30^0
F2	0.574	0.618	14.23	1.20	28^0
F3	0.563	0.620	13.58	1.19	27^0
F4	0.572	0.605	14.27	1.21	26^0

Post compression parameters

Weight variation:

All the formulated (F1 to F4) tablets passed weight variation test as the % weight variation was within the pharmacopoeia limits of ±7.5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values.

Thickness:

Tablets mean thickness were uniform in F1 to F4 formulations and were found to be in the range of 2.2 mm to 2.6 mm.

Hardness:

The measured hardness of tablets of each batch ranged between 3.1 to 3.5 kg/cm^2. This ensures good handling characteristics of all batches.

Friability:

The % Friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

Content Uniformity:

The percentage of drug content for F1 to F4 was found to be between 84.37 % to 87.38 % of Duloxetine , it complies with official specifications.

Disintegration Time:

In the presented studies, three different types of in vitro methods of tablet disintegration were used: those where the only factor leading to the disintegration was water wicking into the matrix of the tablet, the tests with water agitation or stirring, and the methods where direct destructive forces were put on the tested tablet, such as grinding or pressing with additional weight. Therefore, disintegration tests showed great variability in the data measured with different methods.

Table-6: Evaluation parameters of Moringa tablets

F. No.	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Drug content (%)	Disintegration time (min)
F1	250	2.4	3.3	0.27	85.30	17
F2	250	2.6	3.5	0.28	87.38	14
F3	249	2.2	3.1	0.30	86.93	15
F4	251	2.4	3.2	0.26	84.37	19

Dissolution studies

All the 4 formulation of Moringa tablets were subjected to in vitro release studies these studies were carried out using dissolution apparatus. The dissolution medium consisted of 900 ml of Standard buffer pH 6.8 for period of time.

Table-7: Drug release studies of all formulations

Time (min)	F1	F2	F3	F4
0	0	0	0	0
5	18.50	19.67	18.64	17.34
10	27.53	28.10	28.16	28.60
15	35.46	38.16	37.50	37.18
30	53.11	55.10	57.46	56.80
45	65.82	69.49	69.50	68.15
60	94.67	98.52	96.72	93.52

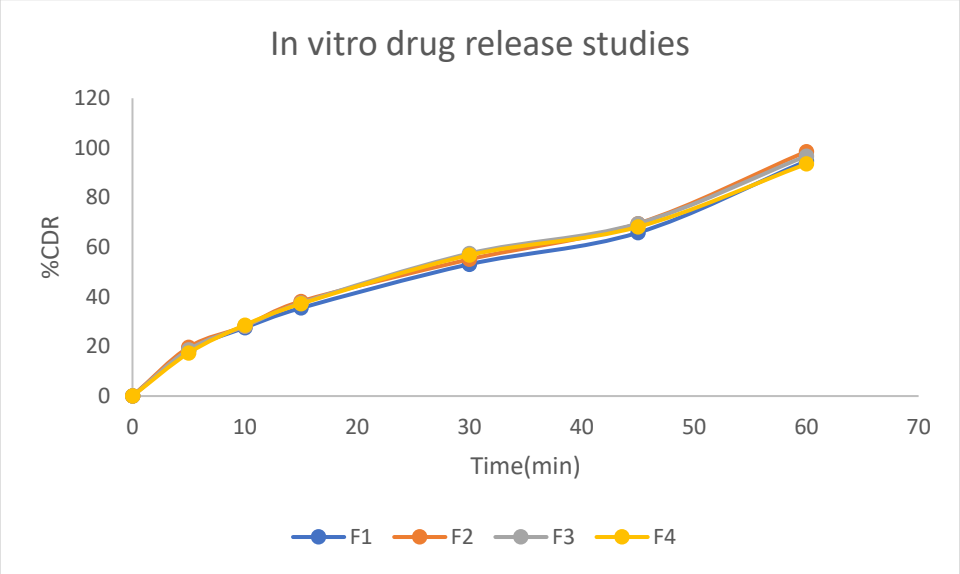


Fig-3: Dissolution Profile of F1 to F4 formulations

Cumulative Drug release of F2 formulation shows 98.52 % within 60min better drug release when compared with other formulations.

Stability Study

There was no significant change in physical and chemical properties of the tablets of formulation F-2 after 90 days. Parameters quantified at various time intervals were shown.

Table-8: Stability studies of all formulations

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-2	**25^{0}C/60%RH % Release**	98.52	97.18	96.57	95.10	**Not less than 85 %**
F-2	**30^{0}C/75% RH % Release**	98.52	97.27	96.19	95.22	**Not less than 85 %**
F-2	**40^{0}C/75% RH % Release**	98.52	97.56	96.45	95.48	**Not less than 85 %**

SUMMARY AND CONCLUSION:

Studies have been carried out for Formulation and Evaluation of Moringa extract tablets for nutritional suppliment by using various excipients. These tablets prepared by using direct compression technique. The prepared tablets were evaluated for weight uniformity, hardness, friability and drug content. The tablets were then evaluated by in vitro

dissolution studies. Selected formulations of Moringa extract were subjected to accelerated stability studies. The formulations were stored at 40 ^{0}C ±20C, 75% ± 5% RH for 3 months. During the accelerated storage condition the tablets were evaluated for physical parameters such as weight uniformity, hardness, friability, drug content and for drug release before and after storage.

The formulation F2 was found to be promising, which shows an in vitro drug release of 98.52% in 60min along with satisfactory results.

From the above experimental results, it can be concluded that tablets of Moringa extract can be prepared by using excipients and we selected F2 as the best formulation based on dissolution profile and physical characteristics. Formulation (F2) showed total drug release in 60min and showed fair flow properties when compared to other formulations.

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