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FORMULATION AND EVALUATION OF TABLETS CONTAINING AQUEOUS LEAF EXTRACT OF *MOMORDICA BALSAMINA* LINN (CUCURBITACEAE) FOR ANTIBACTERIAL ACTIVITY

[1]*Jonathan O. Kadiri, [2]Ignatius S. Okafor, [3]Ikoni J. Ogaji

Department of Pharmaceutical Technology and Industrial Pharmacy, Faculty of Pharmaceutical Sciences, University of Jos, Jos, Nigeria.

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***Corresponding Author**
Jonathan O. Kadiri
Department of Pharmaceutical Technology and Industrial Pharmacy, Faculty of Pharmaceutical Sciences, University of Jos, Jos, Nigeria.

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ABSTRACT

Drugs obtained from natural or synthetic sources are not administered to patients in their crude form but in various dosage forms such as gaseous, liquid, semi-solid and solid dosage forms. They are usually presented in a form which is stable, effective, efficacious and acceptable to the consumers. The aim of this study was to formulate the aqueous leaf extract of *Momordica balsamina* as tablets for oral use, and evaluate the properties of the tablets. The dried leaves were reduced to powder using pestle and mortar. The powder was subjected to extraction with distilled water. The extract was granulated and the granules evaluated for their flow properties. The granules were further formulated into tablets, and the tablet properties evaluated for their physicomechanical properties. The yield was 21% and the granules had good flow properties. The tablets had good physicomechanical properties and best stored in airtight containers.

KEYWORDS: *Momordica balsamina*; granules; tablets; evaluation.

INTRODUCTION

In most cultures from ancient times to the present day, plants are used as source of medicines by man to control diseases in humans and animals. Plants contribute significantly to traditional medicine systems that have been in existence for thousands of years. They

continue to provide humanity with new remedies.[1] It has been estimated by the World Health Organization that approximately 80 % of the world's inhabitants rely mainly on traditional medicines for their primary health care.[1, 2] In Africa, 80 % of the population use medicinal plants as remedies for their effectiveness, and because of the high cost of orthodox drugs.[3] Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations.[4] Drugs obtained from natural or synthetic sources are not administered to patients in their crude form but in various dosage forms such as gaseous, liquid, semi-solid and solid dosage forms. They are usually presented in a form which is stable, effective, efficacious and acceptable to the consumers Herbal preparations or products are given by the practitioners in form of powders, inhalation of powder (snuffing), steam inhalation, macerated products, tinctures (alcohol and water extracts), infusion (hot teas), decoctions (boiled teas),and concoctions.[4] Tablet is an intact dosage form that offers the best capabilities of all oral dosage forms for accuracy in size and content with the lowest variability, lowest cost of manufacture (if it is calculated per dose) and with the lightest, most compact, easiest and most inexpensive way to be packed and shipped.[5]

Momordica balsamina belongs to the dicotyledonae class and the order cucurbitales. It is of the family Cucurbitaceae from the genus Momordica and the species balsamina. It is also known as 'Balsam apple' (African pumpkin) in English. Hausa people call it 'Garahuni', the Igbo call it 'Akbon-ndewe' and the Yoruba call it 'Ejirin.' The extracts from various parts of this plant have been reported to possess shigellocidal, anti-diarrhoeal, antiseptic, antibacterial, antiviral, anti-inflammatory, hypoglycemic and antimicrobial properties.[1,6] The aim of this study was to formulate the aqueous leaf extract of *Momordica balsamina* as tablets for oral use, and evaluate the properties of the tablets.

MATERIALS AND METHODS

MATERIALS

Collection and Authentication of Plant Material

Momordica balsamina leaves were collected from the vicinity of Luka Bentu Indoor Theatre, Tafawa Balewa Street, Jos, Jos North area of Plateau State, North Central Nigeria. The plant was normally collected from the third quarter of the year to the end of the year. It was identified and authenticated by a forestry Instructor, Mr Joseph .J. Azila, of the Federal College of Forestry, Jos, Plateau State where the plant sample was deposited with voucher

number 288. This was confirmed by Mr Namadi Sanusi of the Department of Biological Sciences, Ahmadu Bello University, Zaria, Kaduna State.

METHODS

Preparation and Extraction of *Momordica balsamina* Leaves

The leaves were air-dried in the Pharmaceutical Technology laboratory of the Department of Pharmaceutical Technology and Industrial Pharmacy, University of Jos. The extraction was carried out with 300 g of the powdered *Momordica balsamina* leaves which was weighed out using Adventurer ^{TM} weighing balance (Ohaus AR 2140, China). The leaf powder was extracted with distilled water. The extract was filtered using Whatman No. 1 filter paper. The extract was dried at 40 ^{o}C using water bath placed under fan. The dry material was packaged in a glass bottle and kept in a locker until required for use.

Determination of wavelength of maximum absorbance of the extract

The determination of wavelength of maximum absorbance of the extracts was carried out using the methods of Emeje, Izuka, Isimi, Ofoefule & Kunle[7] and Mishra, Murthy, Sahoo & Sahu.[8] The aqueous extract was serially diluted with distilled water (0.25, 0.125, 0.0625, 0.03125, 0.0156, 0.0078, and 0.0039 mg/mL). A 0.0078 mg/mL of the extracts was chosen for the determination of wavelength of maximum absorbance (λmax) with the aid of Metertech UV-VIS spectrophotometer (Model SP-8001, Taiwan) using distilled water as blank.

FORMULATION AND EVALUATION OF GRANULES AND TABLETS

Preparation of Granules

Before tabletting, preliminary studies were carried out on the formulation using various tablet excipients such as lactose, microcrystalline cellulose, colloidal silicone dioxide, acacia, polyvinylpyrrolidone, starch and magnesium stearate that were used for similar formulations as found in literature. The granules and tablets formed were subjected to some preliminary tests. From the evaluation of the results, the formula in Table 1 was generated for the formulation of the aqueous herbal extract into tablets.

From the formula, the quantity of each ingredient to be used for wet granulation was calculated for hundred tablets and weighed out. These were geometrically triturated and distilled water added to form a wet mass which when pressed in the palm formed a lump and when touched fell apart. The mass was passed through sieve No. 10 (2000 μm) and spread on

a brown paper to dry overnight. The granules were subjected to further drying in an oven at 40^{o}C for 1 h. After drying, they were screened through sieve No. 16 (1190 µm) in preparation for evaluation and subsequent compression.

Table 1: Unit Formula for *Momordica balsamina* Water Extract Tablets.

Ingredient	Concentration (mg)
M. balsamina extract	100 (20 %)
Lactose (%)	275 (55 %)
Maize starch (%)	70 (14 %)
Microcrystalline cellulose	25 (5 %)
Polyvinyl pyrolidone	25 (5 %)
Mg. Stearate (%)	5 (1 %)
Total	500 (100 %)

Evaluation of granules

Flow rate

A quantity of the granules weighing 87 g was transferred into a Pyrex glass funnel and allowed to flow through the length of the funnel and out through the orifice (about a height of 10 cm) onto a brown paper. A stop watch was used to determine the number of seconds or minutes it will take for the entire granules to pass through the funnel orifice.[5] This was repeated six (6) times. The flow rate was calculated as weight of granules divided by the time taken for the entire granules to flow through the funnel orifice. Flow rate was calculated as weight of granules per time (seconds).

Angle of Repose

A quantity of the granules weighing 88.5 g was transferred into a glass funnel and allowed to flow through the length of the funnel and out through the orifice on a brown paper to form a heap. A stick of broom was dip through the middle of the heap in order to determine the height using a ruler to measure the length of the broom. The circumference of the heap was also taken. This was carried out nine (9) times and the mean taken for the height and circumference. The angle of repose was determined using equation 1 and 2.

$\text{Tan}\ \theta = h/r$ 1

$\theta = \text{Tan}^{-1}$ 2

Bulk and tapped densities of the granules

A 50 g quantity of the granules was weighed and carefully transferred into a 100 ml graduated measuring cylinder and the volume recorded. Thereafter, it was tapped until a

constant volume was obtained. This was carried out three (3) times. The bulk density, tapped density, Hausner's ratio and Carr's compressibility index were calculated using equation 3, 4, 5, and 6 respectively.

$$\text{Bulk density} = \frac{\text{Mass}}{\text{Bulk volume}} \quad \text{.......... 3}$$

$$\text{Tapped density} = \frac{\text{Mass}}{\text{Tapped volume}} \quad \text{.......... 4}$$

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}} \quad \text{.......... 5}$$

$$\text{Carr's Compressibility Index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100 \quad \text{.......... 6}$$

True density and porosity of granules

A density bottle of 27 mL capacity was weighed on a weighing balance (Mettler P165, Switzerland) and the weight recorded. The density bottle was then filled with kerosene and the weight determined (W1). A 1 g of the herbal granules was weighed (W2) using the weighing balance. The density bottle was emptied of the kerosene and filled with the 1 g of the herbal granules. The density bottle with the granules was filled with kerosene and the weight (W3) determined. Kerosene was used because the constituents of the granules have little or no dissolution in the non-polar solvent.

The specific gravity of kerosene, true density and porosity of granules were determined as expressed by equation 7, 8, and 9 respectively.

$$Specific\ gravity\ of\ kerosene = \frac{weight\ of\ kerosene}{volume\ of\ kerosene} \quad \text{.......... 7}$$

$$True\ density = \frac{weight\ of\ granules \times specific\ gravity\ of\ kerosene}{(W1 + W2) - W3} \quad \text{.......... 8}$$

$$\text{Porosity}(\phi) = 1 - \frac{\text{Bulk density of granules}}{\text{True density of granules}} \quad \text{.......... 9}$$

Formulation of Tablets

After the evaluation of the granules properties, the herbal granules were compressed into tablets using Erweka tableting machine (Model AR 400, Eko type, Germany) at compression pressures of 5.0, 5.5, and 6.0 metric tons. The tablet were stored in glass bottles until they are required for use.

Evaluation of formulated tablets

Uniformity of diameter

The diameters of the tablets were measured using digital vernier calliper. Twenty tablets were randomly selected from each batch and used for the test. The mean diameter and standard deviation were calculated for each batch.

Uniformity of thickness

The thickness of the tablets was measured using digital vernier caliper. Twenty tablets per batch were selected at random for this. The mean thickness and standard deviation were calculated for each batch.

Weight uniformity test

According to the BP,[9] twenty tablets (20) were weighed individually, and the average weight was calculated. The weights of not more than two tablets should vary from the average weight by the percentage deviation (±5%) and none of the weights should vary from the average weight by more than double that percentage deviation.

Friability test

Appropriate number of tablets were randomly selected per batch and weighed according to the method described in USP.[10] The Roche Friabilator was used for the test. The machine was put on, and the revolving arm was allowed to revolve 25 times per minute for four minutes. The tablets were removed, brushed and blown free from adhering dust and weighed. The experiment was carried out in triplicates per batch. The percentage loss in weight which occurred was taken as a measure of friability.

Hardness test

Monsanto hardness tester was used for the test. Seven tablets from each batch were tested individually for hardness and the mean hardness and standard deviation were calculated.

Disintegration time test

The BP[9] method was adopted using disintegration equipment (Eagle Scientific, England). The disintegration media used were 0.1 N HCl and distilled water. Six tablets were tested for each batch. Each tablet was placed on the screen of the disintegration apparatus immersed in 0.1 N HCl maintained at 37 ± 2 ^{o}C by the equipment. The time required for complete

disintegration of each tablet was taken using a stop watch. The procedure was repeated for the other batches using distilled water.

Dissolution rate test

The BP[9] was adopted. The media used were 0.1 N HCl and water. Nine hundred milliliter (900 mL) of 0.1 N HCl was poured each into 1 litre of the dissolution test station (Model SR II, USA) and maintained at 37 ± 0.5 ^{o}C and 100 rpm. Each tablet of the batches was introduced into the basket arms of the dissolution apparatus. With a 5 mL syringe, samples were withdrawn at intervals of 5, 15, 30, 45 and 60 minutes. The experiment was carried out in triplicate for all the batches. This procedure was also carried out using distilled water for all the batches. The samples were diluted appropriately and the absorbance read on a Metertech UV-VIS spectrophotometer (Model SP-8001, Taiwan) at 215 nm. The concentrations were calculated with reference to the Beer's plot.

Data Analysis

The statistical tools for analysing the data were the student t-test for comparing the means of two independent variables and one way Analysis of Variance (ANOVA) for comparing the means of more than two independent variables at 5 per cent significance level (0.05) using Statistical Package for the Social Sciences (SPSS) software, version 26.

RESULTS AND DISCUSSION

Yield and Characteristic of *Momordica balsamina* Leaf Extracts

The water extract yield of *Momordica balsamina* leaf was 21 %, and was hard, dark brown, lumpy and hygroscopic in nature.

Micromeritic properties

The bulk, tapped and true densities of the granules were 0.5, 0.595 and 1.36 ± 0.1 g/cm^3 respectively (Table 2). They help figure out, to some extent, the difference in size and shape of the granules. Carr's compressibility index, Hausner's ratio and porosity were 16.7 %, 1.19 and 0.63 respectively. Carr's index of 16 - 20 and Hausner's ratio of 1.19 - 1.25 indicate fair flow.[11] The result also reveals that the angle of repose of the herbal granules was 29.5^{o}. It was mentioned by Aulton[11] that the angle of repose of between 25 – 30^{o} indicates excellent flow. It is obvious from the above indicators that the herbal granules exhibit fairly good flow property (6.44 g/ Sec).

Table 2: Flow Properties of Granules of *Momordica balsamina* Water Extract.

S/No	Property	Values
1.	Bulk density (g/cm^3)	0.5
2.	Tapped density (g/cm^3)	0.595
3.	Compressibility (%)	16.67
4	. Hausner's ratio	1.19
5.	Angle of repose (^{O})	29.5
6.	Flow rate (g/sec)	6.44
7.	Porosity (%)	16.6

Tablet properties

The post compression parameters of the tablets (Table 3) show that all the tablet batches did not comply with the BP requirement for tablet weight uniformity. Given the granules properties as evaluated, the disparity in tablet weight was less expected but the variation might be from particle size variation of the granules. Uniformity of weight is very important in tablet formulation because it reflects the consistency or inconsistency of the active ingredient contained in each tablet which can give rise to overdosing or underdosing. For the uniformity of diameter and thickness tests, all the batches passed the BP test of ± 5 % deviation from mean diameter and thickness.[12]

The thickness of the tablets decreased as the compression pressure increased and this resulted in statistically significant ($P < 0.05$) thickness differences among the batches. The uniformity of thickness indicates free flow of granules through the feeder and excellent deposition of granules in the die during compression. The uniformity of diameter indicates that the tablets will pack well in the chosen container by minimizing tight packing of the tablets in such a container thereby preventing cracking and breaking of the tablets under pressure during transportation. Tablet batches compressed at 5.5 and 6.0 metric tons had hardness values of 4.12 ± 0.33 and 7.89 ± 0.75 KgF respectively. The batches demonstrated good hardness quality because oral tablets normally have hardness of 4 – 10 KgF[13] and can withstand the rigors of handling, chipping and transportation. The batch compressed at 5.0 metric tons had hardness value of 2±0.95 kgF and did not pass the test for hardness. All the tablet batches demonstrated good friability values of 0.95±0.28, 0.56±0.26 and 0.46±0.28 % for 5.0, 5.5 and 6.0 metric tons respectively. This indicates the good binding property of the binder in the formulation which helps to minimize chipping and abrasion during transportation.

The disintegration test shows that the aqueous medium gave average disintegration time of 15.87 ± 2.4, 16.50 ± 1.8 and 17.10 ± 1.7 min, and the acidic medium 18.8 ± 2.2, 21.6 ± 2.1

and 22.1 ± 1.9 min for 5.0, 5.5 and 6.0 tons respectively. The aqueous medium had a faster disintegration time than the acidic medium but the disintegration time for both the aqueous and acidic medium did not comply with the BP standard disintegration time of 15 min for uncoated tablet but complied with the USP disintegration time of 30 min. The difference in the mean disintegration time among the three batches using ANOVA was not statistically significant ($p = 0.449$, 95 % CI) for water medium but not so for the acidic medium ($P < 0.05$). The difference in disintegration time between the water and acidic media with the student *t-test* was statistically significant ($P < 0.05$) for all the three batches. The reason for this may not be remote because the starch distintegrant in the formulation would have undergone hydrolysis in the acidic medium causing depolymerization of the amylopectin leading to increase quantity of the linear chains that impede the swelling of the amylopectin portion of the starch which is responsible for the swelling.[14] In the aqueous medium, the amylopectin portion of the starch was not hindered from swelling and this resulted in faster disintegration time when compared with the acidic medium.

Table 3: Post Compression Parameters for *M. balsamina* Tablets.

S/No	Parameters	Compression pressure (metric tons)		
		5.0	**5.5**	**6.0**
1	Uniformity of weight (mg)	499.52±24.9	521.0±26.0	518.28±26
2	Uniformity of diameter (mm)	12.17±0.02	12.13±0.01	12.13±0.01
3	Uniformity of thickness (mm)	4.52±0.04	4.24±0.05	4.05±0.04
4	Hardness (KgF)	2.00±0.95	4.12±0.33	7.89±0.75
5	Friability (%)	0.95±0.28	0.56±0.26	0.46±0.28
6	Disintegration (min) Water	15.87±2.4	16.50±1.80	17.10±1.70
7	HCl	18.8±2.2	21.6±2.10	22.1±1.90

The per cent drug release of the tablet (Table 4 and Fig. 1) over time shows that all the batches released more than 70 % of the active ingredients at 45 min irrespective of the dissolution medium used. It was also found out that there was no significant difference ($p>0.05$) in % drug release among the batches irrespective of the medium used. But the dissolution efficiency (DE) shows that the acidic medium had better DE of 74.3, 72.9 and 67.4 % and aqueous medium had 60.6, 56.6 and 52.8 % for tablets compressed at 5.0, 5.5 and 6.0 metric tons respectively. Consequently, the acidic medium had better DE than the aqueous medium. These indicate that the tablet has good dissolution profile especially in acidic medium and can be taken either on empty stomach or after food.

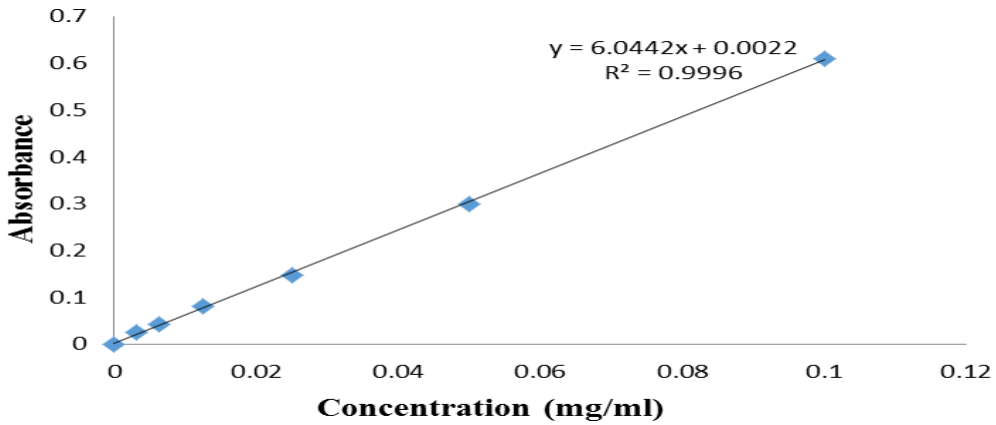


Figure 1: Calibration Curve of Aqueous Extract of *Momordica balsamina* Leaf at 215 nm.

Table 4: In vitro Dissolution Profile of *M. balsamina* Tablets.

S/No	Time (min)	Cumulative % drug release n = 3					
		I		II		III	
		water	HCl	water	HCl	water	HCl
1	5	12.6±3.3	32.5±13.0	8.8±2.5	28.3±7.3	4.1±1.4	22.2±0.6
2	15	41.1±3.4	55.2±4.4	37.3±1.2	54.2±1.6	35.2±0.5	47.4±11.2
3	30	63.5±4.9	79.5± 11.9	59.5±0.5	78.9±2.8	56.9±0.6	71.8±8.1
4	45	89.6±2.0	102.9± 4.8	86.0±2.6	101.5±3.5	81.5±0.6	97±4.4
5	60	97.9±4.4	105.4±3.8	91.2±1.9	104.5±1.3	83.56±1.50	101.4±8.5
6	DE (%)	60.6	74.3	56.6	72.9	52.8	67.4

I = 5 metric tons; II = 5.5 Metric tons; III = 6.0 metric tons; DE= Dissolution efficiency

CONCLUSION

The water extract of *M. balsamina* was formulated into oral tablets that met some official and non-official standards. The tablets compressed at 5.5 and 6.0 metric tons gave the best tablet qualities. The tablets are best stored in dry condition at ambient temperature.

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