IJPSR (2013), Vol. 4, Issue 2 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 14 October, 2012; received in revised form, 26 November, 2012; accepted, 28 January, 2013

DESIGN AND EVALUATION OF COST EFFECTIVE CONVENTIONAL TABLETS FROM *MONECHMA CILIATUM* SEEDS EXTRACT

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Keywords:

Conventional tablets, *Monechma ciliatum*, Cross carmellose cellulose, Preformulation studies, Quality control tests, Ongoing stability studies

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ABSTRACT

The use of medicinal plants as raw material in the production of drugs is again gaining popularity. *Monechma ciliatum* has many traditional uses and applications in African folk's medicines, e.g. the seed's powder macerated in water and drunk or burnt as an inhalation for treatment cold and allergic conditions. The aim of this study is to formulate a suitable dosage form (tablets) from *Monechma ciliatum* seed's ethanolic extract. In the process of formulating of low cost, safe, effective and reproducible dosage form the wet granulation method was used. After preformulation studies, two formulae were prepared, formula-1 by using starch as a binder and disintegrant, formula-2 by using polyvinyl pyrrolidine (PVP) and cross carmellose cellulose (CCS) as a binder and disintegrant respectively. The use of starch as disintegrant in tablets of formula- 1, gave the disintegration time of 8: 33 min: sec, while the disintegration time for tablets of formula- 2 was 11: 667 min: sec by using the high cost super disintegrant CCS. Coloring agent was not needed, as the extract was mutually colored (acceptable pale brown color). Also sweetening agent was not added, as the high content of lactose per tablet masked the bitter taste of the extract. The quality control (QC) tests were carried out and good results were obtained for both formulae. QC test results complied with the requirements stated in official British and American pharmacopeias. The carried out tests were: weight variation, friability, hardness, disintegration and dissolution tests (carried out by using two different dissolution mediums and the dissolution rate was measured at different time intervals). The ongoing stability studies were carried out for tablets of formula-1 and gave positive results.

INTRODUCTION: Infection remains the main cause of morbidity and mortality in man, particularly in under-developed areas where it is associated with poverty and overcrowding. Increased global mobility has aided the spread of infectious disease and allowed previously localized pathogens to establish themselves worldwide.

Deteriorating social conditions in the inner city areas of our major conurbations have facilitated the resurgence of Tuberculosis and other infection. Changes in farming and food processing methods have contributed to an increase in the incidence of food - and water - borne disease. Infectious diseases cause nearly 25% of all human death [1].

Respiratory tract infections are the most common types of infectious diseases in African countries, due to poverty and bad hygiene. The plant *Monechma ciliatum* is distributed throughout tropical Africa, as wild in savanna and also cultivated. In Sudan, it locally known as 'Elmahlab Elaswad', it grows in western and southwestern parts of Sudan, especially in the Nuba Mountains and Gabel Mara area. In Nigeria it is known as 'Bakin mata' in Hausa language.

Monechma ciliatum plays an important role in African folksy medicine in treaing the infectious diseases, the dried leaves and seeds are powdered and burnt as an inhalation for treatment allergies and cold [2]. The seeds of plant contain hydrocarbons and fatty acids as stated by Ayoub [3]. Mariod *et al* [4], screened the seeds chemically, they found fatty acids (palmitic, stearic, linoleic); tocopherols; protein and elements (K, Ca, Mg, Al, Pb, Ni, Mn, Cu, Cr, Co, and Fe). Recently, the seeds were screened by Oshi, *et al* [5], they detected flavonoids, tannins, triterpens, and anthraquinones.

The present study aimed to utilizing information available in Sudanese traditional medicine to formulate this herb into a suitable dosage form, so as to be a useful therapeutic agent to respiratory tract infectious diseases. Extensive experimental work was carried out by Oshi *et al* [5], on the seeds of this herb to select the most suitable extraction methods (maceration, infusion, decoction and hot continuous extraction) for antimicrobial activity tests against gram positive bacteria, gram negative bacteria and fungi, particularly those cause respiratory tract infections.

They concluded that the best extraction method for *Monechma ciliatum* seeds, for antimicrobial activity was maceration method using ethanol 70% (v/v) for 24h as the solvent. Oshi *et al* [5], found the ethanolic extract was highly active against two common bacteria causing respiratory tract infections (Gram positive bacteria *Staphylococcus aureus* and Gram negative bacteria *Klebsiella pneumoniae*).

The oral route is by far the most common means for ingesting drugs into the body. It is also the favored route due to the low cost of drug treatment, management, and patient compliance resulting from convenience of oral drug administration [6].

Compared to other dosage forms, tablets are the manufacturer's dosage form of choice because of their relatively low cost of manufacture, package, and shipment; increased stability; and virtual temper resistance. Tablets are defined as: unit form of solid medicament prepared by compaction. Most consist of a mixture of powder that is compacted in a die to produce a single, rigid body. Although tablets can be defined as a circular disc with either flat or convex faces, they can be produced in a wide variety of size, shapes, and surface marking depending upon the design of punches and dies [7].

MATERIALS AND METHODS

The seed: The seeds of *Monechma ciliatum* were collected from Nubia Mountains (South Kordofan state, Sudan). The seeds were identified and authenticated at the Medicinal and Aromatic Plant Research Institute (MAPRI) of Khartoum-Sudan. The seeds were collected between September and December (autumn season), dried under shade and stored in a covered bottle at room temperature until required for use

Chemicals: Cross carmellose cellulose (A Johnson Matthey, UK), Lactose (Breckland Scientific Supplier, UK), Maize starch (A Johnson Matthey, UK), Magnesium stearate (Breckland Scientific Supplier, UK), Microcrystalline cellulose (A Johnson Matthey, UK), Polyvinyl pyrrolidine (Acros Oragnics, Belgium), Talc (A Johnson Matthey, UK)

Methods:

Preparation of the extract The extract was prepared according to method described by Oshi *et al*, [5], as following: The dried seeds were ground into a powder using mortar and pestle and sieved through mesh No. 35. 20g of the coarse powder weighed, and transferred to flask containing 400mL of 70% (v/v). The flask was allowed for 24h at room temperature, with occasional shaking. Then, the extract of was passed through a cotton wool and the solid residue (marc) pressed (screw press). The strained and expressed liquid obtained were mixed, put for 12h for clarification and filtrated by Whatman filter paper No. 42 (125 mm). Finally, the filtrate was evaporated using rotary evaporator under reduced pressure at 40^{o}C, placed in a Petri dish, and left to dry to constant weight.

Preformulation Studies

1. **Moisture Content:** The moisture content was measured at different points within the manufacturing process by loss on dry (LOD) method. Approximately 5g of sample was uniformly placed onto the sample pan, and then the heating cycle was started. The percentage of moisture was calculated from the weight loss of the sample by heating. The instrument was allowed to cool between tests.

2. **Flow properties:** The flow properties were measured at different points within the manufacturing process by using angle of repose method. 30g of tested material was poured manually into funnel hanged at fixed height 3cm, and then the angle was measured. The test was repeated 3 times [8].

3. **Density:** The bulk density, tapped density and Carr's index of final- blended granules were measured. The bulk and tapped densities of final-blended granule were determined according to the following method: a 50mL glass cylinder was weighed and filled with 30g of powder and reweighed. The opening was secured. The cylinder was gently reversed once, and the powder was carefully leveled without compacting. Bulk volume was determined after one mechanical tap. Tapped volume was measured after 500taps [8].

4. **Particle Size Distribution:** The particle distribution for final- blended granules was measured by sieving method. A 5g of final-blended granule was loaded on to the coarsest sieve of the assembled nest and the nest was subjected to mechanical vibration for 5min [8].

Formulation of Tablet by wet granulation technique

1. **Formula-1: By using maize starch as binder and disintegrant:** Tablets of extract were prepared by wet granulation method according to the formulae given in **Table 1**. All the ingredients were passed through # 60 mesh sieve separately. The extract, microcrystalline cellulose and lactose were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside. Starch paste binder was added gradually to the above mixture, until a good consistence mass was obtained. The mass was forced manually through a No. 10 mesh screen to form granules, which were placed in a hot air oven at 55^{o}C for half an hour. The dried granules were resized using No. 32 mesh screen to get uniform-sized mixture. The starch (disintegrant), magnesium stearate, and talc were added to mixture and remixed for 5 min. The mixture was transferred to a hopper of a single-punch tabletting machine, using die No. 10. The weight and the pressure of the tablets were adjusted to obtain a tablet of 500 mg.

2. **Formula 2: By sing polyvinyl pyrrolidine and cross carmellose cellulose as binder and disintegrant:** Tablets of extract were prepared by wet granulation method according to the formulae given in Table 1. All the ingredients were passed through # 60 mesh sieve separately. The extract, microcrystalline cellulose, lactose and half amount of CCS were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside. PVP 2% (w\v) solution binder was added gradually to the above mixture, until a good consistence mass is obtained. The mass was forced manually through a No. 10 mesh screen to form granules, which were placed in a hot air oven at 55^{o}C for half an hour. The dried granules were resized using No. 32 mesh screen to get uniform-sized mixture. The remainder of CCS, magnesium stearate, and talc were added to mixture and remixed for 5 min. The mixture was transferred to a hopper of a single- punch tabletting machine, using die No. 10. The weight and the pressure of the tablets were adjusted to obtain a tablet of 500 mg.

Quality Control Tests (Post-compression parameters)

1. **Weight Variation Test:** 20 tablets were weighed individually. The average weight of these tablets was calculated, the deviation of each tablet from the mean calculated, from which the standard deviation and percentage deviation calculated and compared with standard [9].

2. **Friability Test:** A sample of 20 tablets was taken and carefully dedusted prior to testing. The tablet sample was accurately weighed and placed in the

drum of apparatus. The drum was rotated 100 times, removed the tablets, the loose dust from the tablets was removed as before, and accurately reweighed. The test was repeated three times, and the mean of the three tests was determined. A maximum mean weight loss from the three samples of not more than 1.0% is considered acceptable for most products [10].

3. **Hardness Test:** 10 tablets were held between a fixed and a moving jaw of hardness test apparatus (Monsanto) and reading of the indicator is adjusted to zero. The screw knob was moved forward until the tablet breaks and the force required breaking the tablet was noted [11].

4. **Disintegration Test:** 1 tablet in each of the six tubes of the basket was placed, a disk to each tube added, and the apparatus operate, using water as medium. The medium was maintained at 37±2°C. At the end of 15 min., the basket was lifted from the fluid, and the tablets examined [10].

5. **Dissolution Test:** The dissolution tester (apparatus 2, 75rpm) was filled with 900mL of 0.1M HCl and water separately as medium, and allowed to warm up to 37±0.5°C. Six tablets were individually introduced into dissolution tester. Then the machine was operated adjusting the rotational speed to 75 rpm. 10 mL of sample was withdrawn in different time intervals (10, 20, 30, 40, 45 min), filtered and assayed using UV method with reference to the standard [10].

6. **Ongoing Stability Studying:** Both disintegration and dissolution tests were done after 3, 6, and 9 months of storage of the tablets in glass bottle at room temperature 30± 2°C and relative humidity 60 ± 5.

RESULTS AND DISCUSSION: The crude extract was formulated as the active ingredient in tablet dosage form using wet granulation method. The whole plant extract was chosen for the test due to the probability of synergistic action. As phytomedicines gain popularity, it is essential to educate the medical and scientific establishment that the pharmacological model of isolating constituents may not be the best methodology for the study of herbal medicines.

If a chemical matrix is necessary for activity in phytomedicines, then many remedies from the purification process from whole plant to isolated constituent may be overlooked. Ultimately, effective research into the mechanisms of actions of phytomedicines will need to account for the possibility, indeed the probability, of synergistic activity between multiple constituents [12].

Ethanolic extract tablets from Monechma ciliatum were prepared by wet granulation technique. Two formulae were designed, formula-1 by using maize starch as a binder and disintegrant and formula-2 by using cross carmellose cellulose as a binder and disintegrant respectively.

The values of preformulation parameters of both formulae evaluated were found to be within the prescribed limits and indicated good free flowability (**Tables 2 to 7**). The data obtained of post-compression parameters such as hardness, thickness, friability, weight variation, disintegration ,dissolution and stability study are shown in (**Tables 8 to 18**) and (**figures 1 to 2**).

Tablets of both formulae were of uniform weight (due to uniform granule particle size distribution and good flow), with acceptable variation as per USP [9] specifications 1.175 and 2.066 for formulae 1and 2 respectively, i.e. below 5%.

The second quality control test was friability test was carried out for tablets of both Formulae (1 and 2) loss percentage of 0.09% and 0.395% obtained respectively, which can be taken as success according to USP [10] which permit loss of up to 1%.

According to method stated by Kiran *et al*, for hardness test, hardness of the tablets of formula-1 was found to be 6.496 kg for three tests, which was within the normal range (4-8kg). For the same test of tablets of formulae-2, a mean of 8.433 kg for three tests, and this was more than normal range mentioned.

The disintegration test revealed that tablets of formula-1 and formula-2 were disintegrated successfully, according to official monographs of USP [10]. Tablets of formula-1 disintegrated in 8.33(min: sec), while formula-2 tablets were disintegrated in 11.667 (min: sec).

Formula-1 tablets were selected for further dissolution and stability studies. As the formulated material was from natural plant origin that needs unusual methods to assay, marker selection method was used for the dissolution test using the UV spectrophotometer at wavelength 275nm for the calibration curve of extract. The absorbencies obtained from the tablets were referred to the curves (Figure 1 and 2), and the percent dissolved calculated in different time intervals (Table 14). 0.01M HCl was better than distilled water as dissolution medium, this was attributed to the relatively weak alkalinity of the extract (pH 7.5). Therefore, 0.01M HCl was proposed as dissolution medium for further stability tests.

Ongoing stability studies were carried out for tablets of formula-1 up to nine months 0, 3, 6, and 9 months) both disintegration and dissolution tests were carried out after storage at room temperature, for three months, six months, and nine months, to assess its stability. Disintegration test results of tablets stored at room temperature is illustrated in Table 15. Table 16 shows the dissolution test results for the stability studies carried out at room temperature during different periods of time. No considerable changes in disintegration and dissolution of tested tablets were detected. The increasing of disintegration time (Table 15) and decreasing of percent dissolved in dissolution test (Table 16) may be attributed to the increase of hardness of tablets for loss of moisture by evaporation.

All quality control tests were analyzed statistically by using SPSS statistical program and no significant changes in all tests ($p<0.05$) recorded.

TABLE 1: FORMULATION DESIGN OF BOTH FORMULAE OF CONVENTIONAL TABLETS OF EXTRACT

S. No.	Composition	Formula-1		Formula-2	
		Weight in tablet (g)	Conc. in tablet (wt%)	Weight in tablet (g)	Conc. in tablet (wt%)
1.	Extract	100	20	100	20
2.	Lactose (as filler)	192	38.4	216	43.2
3.	Microcrystalline cellulose (as filler)	128	25.6	144	28.8
4.	Starch paste (as adhesive)	q.s	-	-	-
5.	Poly vinyl pyrrolidine 2% (w\v) (as adhesive)	-	-	q.s	-
6.	Maize starch (as disintegrant)	50	10	-	-
7.	Cross Carmellose Cellulose (as disintegrant)	-	-	10	2
8.	Magnesium stearate	5	1	5	1
9.	Talc	25	5	25	5
	Total Weight	**500**	**100**	**500**	**100**

TABLE 2: SOME ORGANOLEPTIC PROPERTIES OF THE EXTRACT

Organoleptic Properties	Color	Odor	Taste	Consistency
Description	brown	aromatic	bitter	semisolid

TABLE 3: MOISTURE CONTENT OF PRODUCT OF BOTH FORMULAE

Product Unit	Pre– blended (lactose) LOD %	Wet- mass LOD %	Dry Granule LOD %	Final- blended granule LOD %
Formula- 1	1.4	18.8	1.2	1.5
Formula- 2	1.4	13.7	1.4	1.6

TABLE 4: ANGLE OF REPOSE OF BOTH FORMULAE

Product	Formula- 1			Formula-2		
	Pre- blended (lactose)	Dry- Granule	Final- blended granule	Pre-blended (lactose)	Dry- Granule	Final- blended granule
Angles of repose	50.77°	19.90°	20.80°	50.77°	16.70°	15.64°
	49.09°	22.54°	19.29°	49.090°	16.17°	15.12°
	49.48°	18.93°	18.78°	49.48°	18.26°	16.17°
Mean angle of repose	**49.78°**	**20.47°**	**19.62°**	**49.781°**	**16.38°**	**15.64°**

TABLE 5: THE BULK AND TAPPED DENSITIES OF BOTH FORMULAE

Test No.	Formula-1			Formula-2		
	Weight of 50 mL Graduated Cylinder (g)		Volume occupied by Powder after 500 taps (mL)	Weight of 50 mL Graduated Cylinder (g)		Volume occupied by Powder after 500 taps (mL)
	Empty	Filled to 30 mL		Empty	Filled to 30 mL	
1	71.08	86.08	25.00	71.08	86.07	24.00
2	71.12	86.10	25.00	71.12	86.08	24.00
3	71.10	86.08	24.00	71.10	86.07	24.00
Mean	71.10	86.09	24.67	71.10	86.07	24.00

TABLE 6: CARR'S INDEX OF FINAL- BLENDED GRANULE OF BOTH FORMULAE

Product	Formula-1	Formula-2
Bulk Density (g cm^{-3})	0.52	0.53
Tapped Density (g cm^{-3})	0.61	0.62
Carr's Index	14.75	14.52

TABLE 7: PARTICLE SIZE DISTRIBUTIONS OF FINAL- BLENDED GRANULE OF BOTH FORMULAE

Mesh No.	Aperture Size Range / Mean (µm)	Formula- 1		Formula- 2	
		Weight (gm) or Frequency	Percent Frequency (%)	Weight (gm) or Frequency	Percent Frequency (%)
24	600- 850 µm, 710 µm	0.2	4.17	0.2	4.25
32	425 -600 µm, 500 µm	0.9	18.75	0.5	10.62
42	300- 425 µm, 355 µm	1.9	39.58	2.2	46.71
60	212 -300 µm, 250 µm	1.5	31.25	1.7	36.09
80	150 -212 µm, 180 µm	0.2	4.17	0.1	2.12
100	125 -180 µm, 150 µm	0.1	2.08	0.01	0.12

TABLE 8: WEIGHT VARIATION TEST RESULTS FOR THE THREE BATCHES OF TABLETS OF BOTH FORMULAE

Tab. No.	Formula- 1			Formula- 2		
	Tablet Weight			Tablet Weight		
	Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
1	0.508	0.497	0.497	0.506	0.507	0.506
2	0.505	0.499	0.499	0.493	0.497	0.490
3	0.501	0.489	0.489	0.507	0.499	0.506
4	0.489	0.490	0.490	0.499	0.490	0.503
5	0.503	0.506	0.506	0.516	0.513	0.508
6	0.494	0.505	0.505	0.511	0.487	0.505
7	0.508	0.490	0.490	0.506	0.502	0.501
8	0.502	0.490	0.490	0.496	0.492	0.520
9	0.501	0.505	0.505	0.509	0.495	0.504
10	0.506	0.498	0.498	0.512	0.481	0.501
11	0.501	0.492	0.492	0.503	0.494	0.500
12	0.507	0.496	0.496	0.508	0.508	0.499
13	0.505	0.502	0.502	0.508	0.502	0.499
14	0.500	0.489	0.489	0.509	0.433	0.499
15	0.500	0.505	0.505	0.489	0.496	0.499
16	0.489	0.489	0.489	0.488	0.499	0.508
17	0.503	0.506	0.506	0.507	0.507	0.514
18	0.505	0.492	0.492	0.503	0.497	0.509
19	0.500	0.499	0.499	0.502	0.499	0.516
20	0.490	0.500	0.500	0.505	0.487	0.496
∑ X	**10.017**	**9.939**	**9.939**	**10.077**	**9.885**	**10.083**
Mean, $\bar{X}$	**0.501**	**0.497**	**0.497**	**0.504**	**0.494**	**0.504**
$\sum (X-\bar{X})^2$	**0.000677**	**0.000787**	**0.000509**	**0.001054**	**0.005078**	**0.000961**

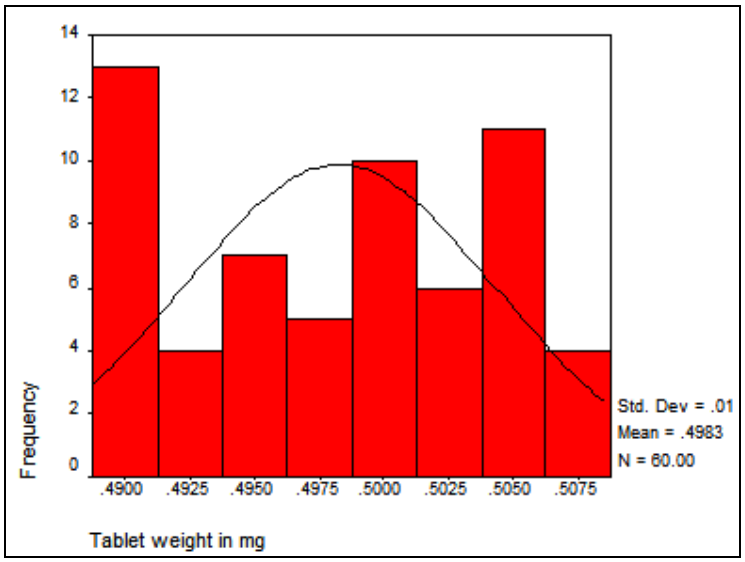
The Calculated Standard Deviation (SD) = $\sqrt{\sum(x-\bar{x})^2 / n-1}$

For formula-1
SD_1= √0.000677/ 19 = 0.00597; SD_2= √0.000787/ 19 = 0.00644; SD_3= √0.000509/ 19 = 0.00508

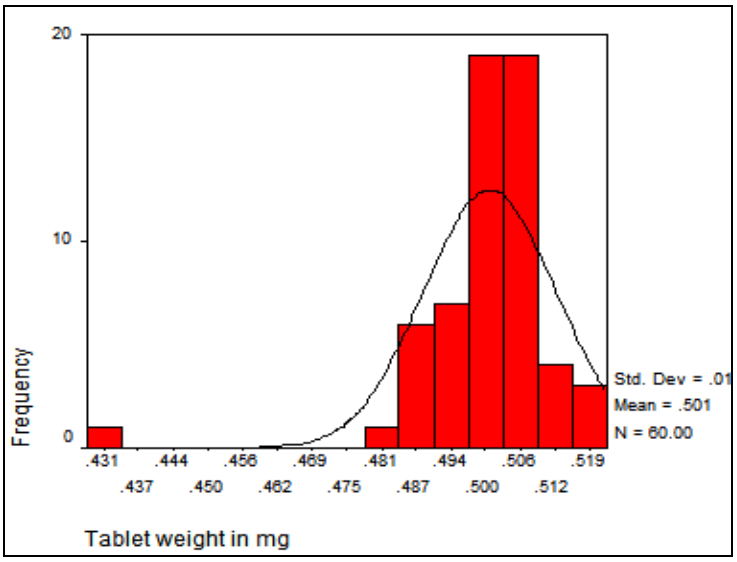
For formula-2
SD_1= √0.001054/ 19 = 0.00744; SD_2= √0.005078/ 19 = 0.01635; SD_3= √0.000961/ 19 = 0.00710

TABLE 9: THE STANDARD DEVIATION AND PERCENT DEVIATION FOR BOTH FORMULAE

Test No.	Formula- 1		Formula- 2	
	SD = $\sqrt{\sum(x-\bar{x})^2 / n-1}$	% D= SD x 100 / Average wt.	SD = $\sqrt{\sum(x-\bar{x})^2 / n-1}$	% D=SD x100 / Average wt.
Batch-1	0.00597	1.192	0.00744	1.477
Batch-2	0.00644	1.296	0.01635	3.310
Batch-3	0.00508	1.042	0.00710	1.410
Mean= $SD_1+SD_2+SD_3/3$	**0.00586**	**1.175**	**0.01030**	**2.066**



GRAPH 1: WEIGHT VARIATION STATISTICAL ANALYSIS OF TABLETS OF FORMULA- 1 USING SPSS COMPUTER PROGRAM



GRAPH 2: WEIGHT VARIATION STATISTICAL ANALYSIS OF TABLETS OF FORMULA- 2 USING SPSS COMPUTER PROGRAM

TABLE 10: STATISTICAL ANALYSIS OF WEIGHT VARIATION TEST FOR BOTH FORMULAE USING INDEPENDENT SAMPLE TEST

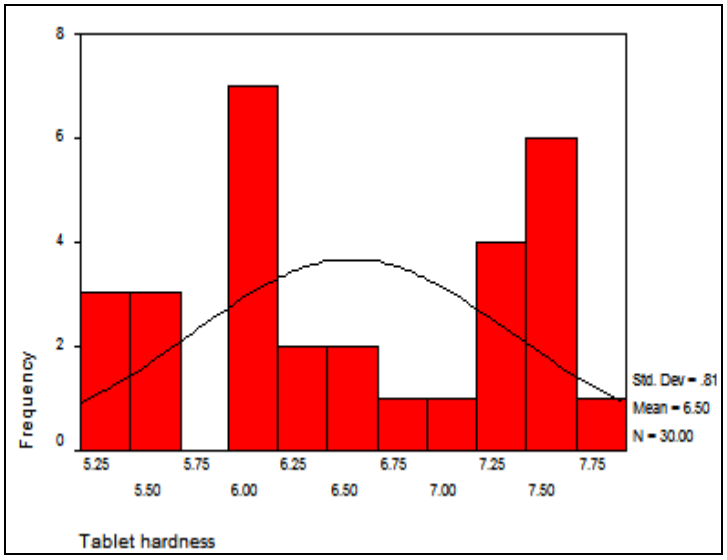
	Test Value = 0					
	T	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Formula- 1	598.519	59	.000	.49825	.4966	.4999
Formula- 2	324.703	59	.000	.50075	.4977	.5038

TABLE 11: FRIABILITY TEST RESULTS OF TABLETS OF BOTH FORMULAE

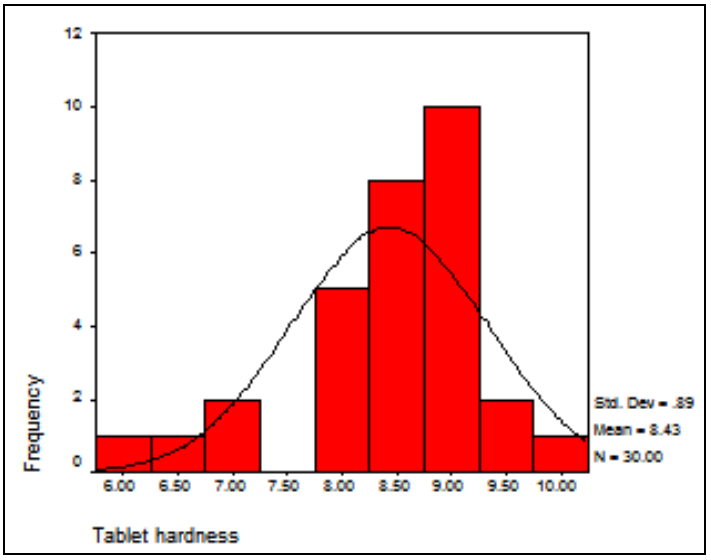
Test No.	Formula- 1				Formula- 2			
	Wt. of 20 tablets before test (X_1)	Wt. of 20 tablets after test (X_2)	(X_1- X_2)	Weight loss %	Wt. of 20 tablets before test (X_1)	Wt. of 20 tablets after test (X_2)	(X_1- X_2)	Weight loss %
Batch-1	10.020	10.012	0.008	0.080	10.049	10.012	0.037	0.368
Batch-2	10.030	10.012	0.009	0.090	10.020	9.995	0.025	0.250
Batch-3	10.000	10.010	0.010	0.100	10.057	10.00	0.057	0.567
Mean= $SD_1+SD_2+SD_3/3$				**0.09**				**0.395**

TABLE 12: HARDNESS TEST RESULTS FOR TABLETS OF BOTH FORMULAE

Tablet No.	Formula-1			Formula-2		
	T_1	T_2	T_3	T_1	T_2	T_3
1	7.58	5.20	7.20	8.08	6.75	8.28
2	7.52	6.41	5.93	9.07	8.54	9.11
3	5.99	6.37	6.63	8.92	9.11	8.47
4	6.37	5.19	7.39	8.15	8.54	9.11
5	7.39	7.84	7.45	7.90	9.75	9.43
6	6.12	6.61	6.05	8.54	8.92	8.98
7	7.14	5.90	5.40	6.05	7.07	7.90
8	5.27	7.14	7.14	8.92	8.86	7.90
9	5.59	5.93	7.58	9.37	8.66	8.73
10	6.05	5.61	6.88	9.17	6.37	8.35
Mean	**6.502**	**6.22**	**6.765**	**8.417**	**8.257**	**8.626**
Mean = $\frac{T1+T2+T3}{3}$	**6.496 kg**			**8.433 kg**		



GRAPH 3: HARDNESS STATISTICAL ANALYSIS GRAPH FOR TABLETS FOR TABLETS OF BOTH FORMULA-1 USING SPSS COMPUTER PROGRAM



GRAPH 4: HARDNESS STATISTICAL ANALYSIS GRAPH FOR TABLETS FOR TABLETS OF BOTH FORMULA-2 USING SPSS COMPUTER PROGRAM

TABLE 13: STATISTICAL ANALYSIS OF HARDNESS TEST FOR BOTH FORMULAE USING INDEPENDENT SAMPLE TEST

	Test Value = 0					
	T	Df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Formula- 1	43.774	29	.000	6.49567	6.1922	6.7992
Formula- 2	51.855	29	.000	8.43333	8.1007	8.7660

TABLE 14: DISINTEGRATION TEST RESULTS FOR TABLETS OF BOTH FORMULAE

Test No.	Formula-1: Disintegration time (min: sec)	Formula-2: Disintegration time (min: sec)
1	8.00	11.00
2	9.00	12.00
3	8.00	12.00
Mean	**8.33**	**11.667**

TABLE 15: THE ABSORBANCE DATA BY USING HCL AND WATER AS DISSOLUTION MEDIUM

S. No.	Concentration (mg/mL)	Absorbance in 0.1N hydrochloric acid	Absorbance in distilled water
1	0.03	0.179	0.164
2	0.06	0.319	0.301
3	0.09	0.474	0.422
4	0.12	0.621	0.60
5	0.15	0.763	0.67

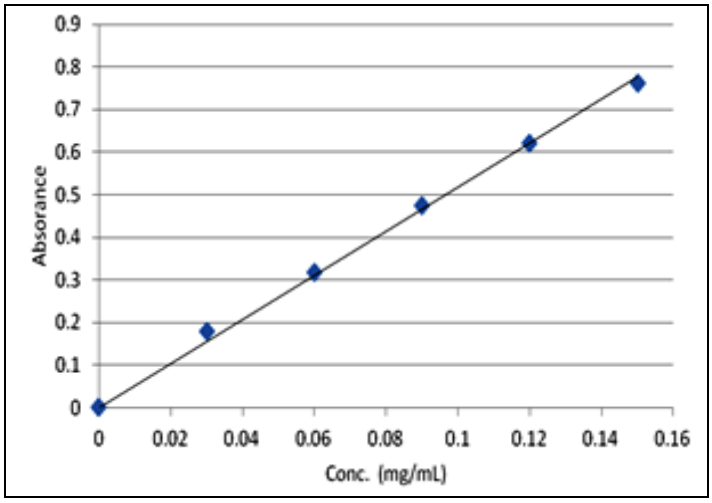


FIGURE 1: COMPUTERIZED CALIBRATION CURVE OF FRESH EXTRACT USING 0.1N HYDROCHLORIC ACID (ABSORBANCE DATA, USING SERIAL CONCENTRATIONS OBTAINED FROM A FRESH EXTRACT 0.02GM/100ML OF 0.1N HYDROCHLORIC ACID

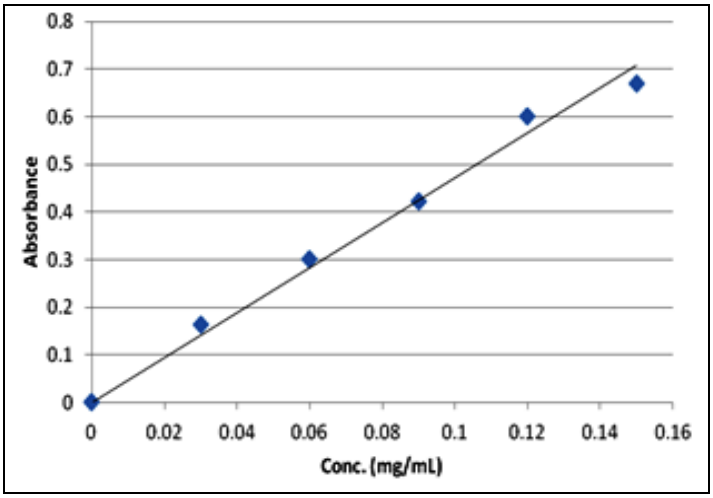


FIGURE 2: COMPUTERIZED CALIBRATION CURVE FOR DATA OBTAINED USING SERIAL CONCENTRATIONS, OBTAINED FROM FRESH EXTRACT 0.02GM/100ML OF DISTILLED WATER, USING 275 NM

TABLE 16: THE MEAN ABSORBANCE OF 6 TABLETS IN DIFFERENT TIME INTERVALS BY USING 0.1N HYDROCHLORIC ACID AS DISSOLUTION MEDIUM

Time interval of dissolution test	Hydrochloric acid			Water		
	Mean of absorbance of 6 reading	Amount of drug	Percent dissolved	Mean of absorbance of 6 reading	Amount of drug	Percent dissolved
After 10 mins	0.472	0.64664	64.66	0.398	0.6130	61.30
After 20 mins	0.480	0.6576	65.76	0.407	0.62678	62.678
After 30 mins	0.498	0.68226	68.23	0.477	0.7346	73.46
After 40 mins	0.500	0.6850	68.5	0.489	0.75306	75.306
After 45 mins	0.610	0.8357	83.57	0.499	0.76846	76.846

* Drug dissolved = $\frac{\text{The amount of the drug released in specified time X 100}}{\text{Total content of drug per tablet}}$

* Amount of drug = Absorbance (A) × Calibration factor (CF) × Dilution factor (DF)

* Calibration factor = $\frac{1}{\text{slope}}$ = 1.370 (Using hydrochloric acid as dissolution medium)

* Calibration factor = $\frac{1}{\text{slope}}$ = 1.540 (Using distilled water as dissolution medium)

TABLE 17: DISINTEGRATION TEST RESULT FOR TABLETS OF FORMULA-1

Disintegration test No.	Time of the test	Disintegration time (minutes: seconds)
T_1	At zero time	8.33
T_2	After three months	9.30
T_3	After six months	11.50
T_4	After nine months	13.47

TABLE 18: DISSOLUTION TEST RESULT FOR TABLETS OF FORMULA-1

Test No.	Time of the test	Absorbance after 45 minutes	Amount of the drug	Percent dissolved
T_1	At zero time	0.610	0.8357	83.57
T_2	After three months	0.605	0.82885	82.85
T_3	After six months	0.598	0.81926	81.92
T_4	After nine months	0.580	0.7946	79.46

CONCLUSION: Tablet of both formulae complied with the standard requirements of precompression parameters (flow properties, density, particle size …) and post-compression parameters (weight variation, friability, hardness, disintegration, and dissolution). A cost effective formulation was adopted using starch as binder and disintegrant. The high hardness test results shown in tablets of formula- 2, was attributed to the presence of the polymer PVP as binder. The formulated tablet did not need coating as the bitter taste of the extract was masked by the relative high amount of lactose per tablet.

The dissolution test of tablets of formula-1 was carried out to assay the amount of the dissolved ingredients, by measuring the amount of the dissolved ingredients in different time intervals (10, 20, 30, 40, and 45 minutes), which gave positive scientific prediction about the pharmacokinetics and bioavailability. Tablets of formula- 1 were stable for nine months as shown in the ongoing stability results. It could be concluded that the starch based tablets of extract would be quite effective that superdisintegrant based tablets of extract (more acceptable precompression and post compression parameters).

Further optimization of excipients concentration of tablets of formula- 1 is strongly recommended by using ANOVA system.

ACKNOWLEDGMENT: The authors are thankful to department of Pharmaceutical Technology, faculty of Pharmacy- Omdurman Islamic University for providing excellent facilities to carry out this work.

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How to cite this article:
Oshi MAM and Abdelkareem AM: Design and Evaluation of Cost Effective Conventional Tablets from *Monechma ciliatum* seeds extract. *Int J Pharm Sci Res*. 2013; 4(2); 634-643.