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EVALUATION OF THE BINDING PROPERTY OF *SIDA ACUTA* GUM IN PARACETAMOL TABLET FORMULATIONS

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ABSTRACT

The study was done to evaluate the binding property of different concentrations of *Sida acuta* gum (SAG) in paracetamol tablet formulations and to compare it to standard gums. SAG was extracted from powdered dried leaves of *Sida acuta* macerated in distilled water. Paracetamol tablets were prepared by wet granulation using SAG (0 - 2%), Corn starch mucilage (1.5 -2%) and hydroxypropylmethylcellulose, HPMC (1.5 -2%) as binders respectively. They were evaluated based on official and unofficial tests. The paracetamol granules showed passable to excellent flow property. The tablets have hardness values from 3.5 ± 0.00 to 6.75 ± 0.35 Kgf (SAG), 3.75 ± 0.35 to 4.0 ± 1.41 Kgf (starch mucilage), 2.75 ± 0.35 to 3.5 ± 0.00 Kgf (HPMC) and 0.35 Kgf (0 % binder). Tablet friability was less than 1 % for all formulations except P9 (3.18 %) that contained no binder. The % weight deviation for all the formulations ranged from 0.00 to 3.33%. The disintegration time (min) for the tablets ranged from 6.33 ± 5.86 to 49.00 ± 1.00 (SAG), 1.39 ± 0.10 to 1.53 ± 0.13 (Starch mucilage), 0.49 ± 0.08 to 0.79 ± 0.04 (HPMC) and 0.50 ± 0.00 (zero binder). The drug content of the formulations was found to be between 97.2 to 102 %. All the formulations released more than 75 % of their drug contents within 45 min. The binding property of SAG in paracetamol tablet formulations increases with increase in concentration.

KEYWORDS: Binding property, paracetamol, *Sida acuta* gum, tablets, evaluation.

INTRODUCTION

A tablet is composed of the active ingredient(s) and other substances, known as excipients, which have specific functions. The different types of excipients which are normally added into tablet formulations are; diluents, adsorbents, moistening agents, binding agents, glidants, lubricants and disintegrating agents.[1, 2]

Binders are glues that hold powders together to form granules. They are agents employed to impart cohesiveness to the granules.[1, 2, 3] Binders are added to tablet formulation to impart plasticity and thus increase the interparticulate bonding strength within the tablet. [4] They ensure that granules and tablets are formed with the required mechanical strength. This ensures improvement in the flow property of the granules, as well as that the tablet remains intact after compression. The choice of a suitable binder for a tablet formulation requires extensive knowledge of the relative importance of binder properties for enhancing the strength of the tablet and also of the interactions between the various materials constituting a tablet.[1, 2, 3, 4, 5, 6]

Binders are used either in solutions or dry form depending on the other ingredients in the formulations and the method of preparation especially in wet granulation to form granules or to promote cohesive compacts for directly compressed tablets. As dry powder, they are mixed with other ingredient(s) before wet granulation or in dry granulation (roller compaction, slugging).

As solution binders, they are dissolved or dispersed in the granulating fluid and then incorporated as a solution or dispersion. Water is the most common granulating fluid, but it is seldom used as a co-solvent with ethanol. Binders can be insoluble in water, e.g. starch, soluble in water e.g. HPMC or soluble in both water and ethanol e.g. polyvinylpyrrolidone (PVP) or hydroxypropylcellulose.[1, 2, 7, 8] The quantity of binders used has a considerable influence on the characteristics of the compressed tablets.[5, 9] Increasing the binder concentration invariably increases the disintegration time.[10] Corn starch is the most widely used excipient in the production of tablets and hence is utilized as disintegrants, fillers or binders.[11, 12]

Important materials commonly used as binders are starch, gelatin, natural gums, sugar, acacia sodium alginate, methylcellulose, microcrystalline cellulose, polyethylene glycol, waxes and water.[5, 13] They are classified into natural polymers e.g. starch, pregelatinized starch, gelatin,

acacia, tragacanth, okro and irvingia gums; synthetic polymer e.g. PVP, HPMC, methyl cellulose, ethyl cellulose, polyethylene glycol; and Sugar e.g glucose, sucrose, sorbitol.[4] Different plant gums and mucilages have been used as binders in the formulation of various active pharmaceutical ingredients into tablets. The use of *mucuna* gum as a binder in formulation of sulphadimidine and chloroquine phosphate tablets has been studied.[14] Grewia gum was used as a binder in the production of sodium salicylate tablets.[15] Paracetamol tablet produced by using Manihot esculenta starch as binder was better in friability and hardness than that produced with industrial starch (Maize).[8] *Cissus populnea* and *Acassia senegal gums* displayed good tableting characteristics and have high potentials for substitution for other more expensive binders like maize starch commonly used as binders in tablet formulation.[16] The binder solution prepared by dissolving the mucilage of *Ziziphus mauritiana* and *Aegle marmelos* in water at 10%, 20% 30% w/v concentration were used in preparing paracetamol tablets.[17] *Artocarpus heterophyllus* was evaluated as a binder in the preparation of paracetamol tablets. It was observed that the tablets prepared with 6.0 %w/v *A. heterophyllus* showed hardness nearly equal to the tablet prepared by using 6.0 % w/v of starch gum.[18]

The development of new excipients for potential use as binding agent in tablet formulations continues to be of interest. This is because different binding agents can be useful in achieving various tablet mechanical strength and drug release properties for different pharmaceutical purpose.[4]

Sida acuta Burm. F is a shrub that belongs to the *Malvaceae* family. The plant is widely distributed in the subtropical regions where it is found in bushes, in farms and around habitations.[19] *Sida acuta* gum could be isolated from the powdered dried leaves of *Sida acuta*. The gum has physicochemical properties that showed that it could be used as pharmaceutical excipient such as binder, suspending agent or swellable hydrophilic matrix former.[20]

This study was conducted to evaluate the binding property of *Sida acuta* gum in paracetamol tablet formulations.

MATERIALS AND METHOD

Materials

Isopropyl alcohol, acetone, (Guangxing Guanghua Chemical, China), conc. Hydrochloric acid, (Haig Laboratory Chemical Corporation Wembley, MIDDX, England, paracetamol (Changsh Huagang Pharm. Co, China) was received as a gift from Orange Kalbe Limited , Lagos, hydroxylpropylmethylcellulose, magnesium stearate, (Loba Chemie, Mumbia, India), corn starch were of analytical grades. *Sida acuta* leaves were collected from plants in bushes within the New G.R.A area of Trans – Ekulu, Enugu, Enugu state, Nigeria.

Extraction and purification of *Sida acuta* gum

Sida acuta gum was extracted and purified from the dried powdered leaves of *Sida acuta* macerated in distilled water using the method of.[20]

Preparation of paracetamol tablets

Paracetamol tablets were prepared by wet granulation method using the formula on Table 1. *Sida acuta* gum was used in different concentrations (0.5, 1, 1.5 and 2%) as binder to prepare granules for formulations P1, P2, P3 and P4 respectively. Starch mucilage and hydroxypropyl - methylcellulose were also used in concentrations of 1.5 and 2% as binders in the preparation of granules for formulations P5, P6, P7, and P8.respectively. Formulation P9 contained no binder. The paracetamol powder and the excipients were passed through 300 µm sieve respectively. The granules were formed by mixing the paracetamol powder thoroughly with the lactose and half of the required quantity of corn starch. The corn starch which served as the disintegrant was divided into two portions and added intra- and extra – granularly. The respective binder powder was dispersed in little water to form the binder solution. The binder solution was added to the powder – mix and blended thoroughly to form a damp mass. The damp mass was passed through 1.18 mm sieve to form wet granules. The granules were dried in the oven at 50^0C for 2 h. The dried granules were passed through 710 µm sieve. The granules were mixed with the remaining part of corn starch, talc and magnesium stearate and compressed into the respective tablets with a force of 27.4kN, using a CJD 316 sixteen station rotary tablet press (Clit Jemkay Engs. Pvt, Ltd. Ahmedabad, India) having a 13 mm punch.

Table 1: Compositions of paracetamol tablets for formulations P 1 to P 9.

INGREDIENTS	P 1	P 2	P 3	P 4	P 5	P 6	P 7	P 8	P 9
PARACETAMOL (mg)	500	500	500	500	500	500	500	500	500
SAG (mg)	3	6	9	12	0	0	0	0	0
STARCH MUCILAGE (mg)	0	0	0	0	9	12	0	0	0
HPMC (mg)	0	0	0	0	0	0	9	12	0
CORN STARCH (mg)	60	60	60	60	60	60	60	60	60
LACTOSE (mg)	29.5	26.5	23.5	20.5	23.5	20.5	23.5	20.5	32.5
TALC (mg)	6	6	6	6	6	6	6	6	6
MAGNESIUM SILICATE (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
TOTAL (mg)	600	600	600	600	600	600	600	600	600

Key: HPMC = Hydroxylpropylmethylcellulose, SAG =Sida acuta gum.

Evaluation Of Granules

Granules to be used for the preparation of the different formulations of paracetamol tablets were characterised based on their angle of repose, bulk density, tapped density, Carr's compressibility index, Hausner's ratio, and particle size distribution.

Determination of the angle of repose of the granules

This was determined by the funnel method. A funnel was clamped to a retort stand at a height of 7.5 cm above the table. A 10 g sample of paracetamol granules was weighed and poured into the funnel with the tip closed. The funnel was opened and granules were allowed to flow through, and they formed a cone on paper placed beneath it. The height and diameter of the cone were recorded. The angle of repose, θ was determined using equation 1. This was done in triplicate.

$$\theta = \text{Tan}^{-1}\ \frac{h}{r} \quad \ldots\ldots\ldots\ldots \quad 1$$

Where, h = height of cone and r = radius of the cone.

Determination of the bulk and tapped densities of the granules

A 10 g paracetamol granules was weighed and poured into a 50 ml graduated cylinder and the bulk volume recorded. The cylinder was tapped 100 times and the tapped volume was recorded. The bulk and tapped densities were calculated. This was done three times.

$$\text{Bulk density} = \frac{weight\ of\ granules}{bulk\ voulume\ of\ granules} \quad \ldots\ldots\ldots\ldots \quad 2$$

Tapped density = $\frac{Weight\ of\ granules}{Tapped\ volume\ of\ granules}$ **3**

Determination of Carr's compressibility index for the granules

This was calculated from the bulk and tapped densities using equation 4

$$\%\ Compressibility = \frac{(D1-D2)\ X\ 100}{D1}$$ 4

Where D1= Tapped density, and D2 = Bulk density

Determination of Hausner ratio for the granules

This was also calculated from the bulk and tapped densities using equation 5.

$$Hausner\ Ratio = \frac{Tapped\ density}{Bulk\ density}$$

..... 5

Granules size analysis

Each batch of dry granules for the respective formulations was passed through a nest of stainless steel laboratory test sieves (Endecott) suitably arranged on an Endecott's minor 2165-09 sieve vibrator (Endecotts Ltd, London, England). The nest of sieves was made to vibrate for 10 min to separate the granules into various size fractions (< 125, 125 – 149, 150 – 179, 180 – 424, 425 – 499, > 500 µm).

Evaluation of tablets

The compressed tablets were evaluated based on official and unofficial tests.

Tablets weight variation test

Twenty tablets were selected randomly from respective formulations and weighed individually. The individual weights were compared with the average weight for weight variation.

Tablets thickness test

Ten tablets from each formulation were taken randomly and their thickness measured using a digital tablet thickness test apparatus (Veego tablet test apparatus, India).

Tablet hardness test

Five tablets were selected randomly from each formulation and hardness was determined using a digital tablet hardness test apparatus (Veego tablet test apparatus, India).

Tablet friability test

The friability of the prepared tablets was evaluated as the percentage weight loss of 10 tablets tumbled in a friabilator (Veego friability test apparatus, India) for 4 min at 24 rpm.

Tablets disintegration time test

From each of the paracetamol formulations, six tablets were picked at random and placed in the six respective tubes of the tablet disintegration test apparatus (Manesty, Liverpool, England). The tablets were repeatedly lowered into, and lifted up from the disintegration medium composed of distilled water, maintained at 37 ± 2^0C, until all the tablets broke up and passed through the sieve at the base of each tube. The mean disintegration value obtained for the six tablets was recorded.

Drug content of tablets

Drug content of compressed tablets was determined by UV Spectrophotometric method.

Ten (10) tablets from each formulation were accurately weighed and crushed in a mortar with pestle. Quantity of powder that contained equivalent of 100 mg of paracetamol was weighed and dissolved in 100 ml of 0.1 N hydrochloric acid (HCl). This was filtered through a 0.45-µm filter paper. The filtrate was diluted with 0.1 N HCl. The drug content was analyzed spectrophotometrically at 242.4 nm using an UV – VIS spectrophotometer (UV - 1800, Shimadzu Japan) and the absorbance value compared with a reference standard curve of paracetamol.

In vitro dissolution studies

This was carried out using USP XX type 1 (Rotary basket) apparatus. One tablet of paracetamol was weighed and placed in the basket of a single unit Copley dissolution test apparatus (Erweka Apparatebau GMBH, Heusengtamm, Germany). The basket was inserted into the dissolution chamber that contained 0.1 N HCl maintained at 37 ± 1^0C as the dissolution medium and rotated at a speed of 100 rpm. A 5 ml sample was withdrawn and replaced with 5 ml of fresh pre- heated dissolution medium after 10, 20, 30, 45 and 60 min. The sample was analyzed using UV spectrophotometer. The pure sample of paracetamol was used to scan for maximum wavelength (γ) of absorption and the obtained value 242.4 nm was used in the analysis. The in vitro dissolution test was repeated twice for all the paracetamol tablet formulations.

Stability Studies

Tablets from the optimized formulation, P1 were kept in airtight containers at room temperature for a year. Tablet samples were taken after 6 and 12 months and subjected to assay and *in vitro* dissolution test analysis.

Analysis of Data

Statistical analysis was done using Microsoft Excel and SPSS version 22.0. Data were analysed by one – way ANOVA. Differences between means were assessed by a two – tailed student's t – test. $P < 0.05$ was considered statistically significant.

RESULTS AND DISCUSSION

Evaluation of granules

As shown on Table 2, granules from formulations P2 and P4 had angles of repose that were between 25 and 30. Formulations P1, P3, P5, P6, P7, P8, and P9 had angles of repose that were between 30 and 40 which indicated passable flow. All the granules for the different formulations had Hausner ratio of less than 1.25 which indicated good flow.

Granules from all the formulations except P7 and P9 had Carr's index of less than 15 which indicated excellent flow property. Formulation P7 had Carr's index of 15.12 ± 0.74 which indicated good flow, while formulation P9 had Carr's index of 17.28 ± 2.14 which indicated passable flow.

Table 2: Powder characterisation for paracetamol tablets (Formulations P 1 to P 9).

	ANGLE OF REPOSE ± S.D	BULK DENSITY ± S.D	TAPPED DENSITY ± S.D	HAUSNER RATIO ± S.D	CARR'S INDEX ± S.D
P1	32.75 ± 0.23	0.38 ± 0.01	0.44 ± 0.01	1.16 ± 0.03	13.91 ± 2.08
P2	29.68 ± 0.74	0.42 ± 0.01	0.44 ± 0.01	1.05 ± 0.01	4.93 ± 1.25
P3	30.11 ± 0.74	0.41 ± 0.01	0.45 ± 0.00	1.10 ± 0.03	8.91 ± 2.85
P4	25.48 ± 0.54	0.53 ± 0.02	0.57 ± 0.02	1.07 ± 0.02	6.21 ± 1.65
P5	30.96 ± 0.00	0.42 ± 0.01	0.43 ± 0.01	1.04 ± 0.01	3.47 ± 1.13
P6	30.53 ± 0.74	0.43 ± 0.01	0.46 ± 0.02	1.06 ± 0.03	5.74 ± 2.56
P7	30.10 ± 1.29	0.39 ± 0.01	0.47 ± 0.01	1.18 ± 0.01	15.12 ± 0.74
P8	31.79 ± 0.72	0.38 ± 0.01	0.43 ± 0.01	1.14 ± 0.01	12.49 ± 2.03
P9	30.39 ± 0.49	0.37 ± 0.00	0.45 ± 0.45	1.21 ± 0.03	17.28 ± 2.14

Hardness

Hardness is an important characteristic to be evaluated to ascertain the tablets ability to withstand further handling and transportation challenges. The hardness of the tablets from formulation P1 to P9 were as shown on Table 3. This showed that the tablets from formulations P2 to P4 that contained 1 to 2% of *Sida acuta* gum and P6 that contained 2% starch mucilage passed the hardness test since they have hardness values of 4 kgf and above. For all the formulations studied, tablet hardness increased with increase in the concentration of the binder, P1 to P4 (3.5 ± 0.00 to 6.75 ± 0.35 Kgf), P5 to P6 (3.75 ± 0.35 to 4.0 ± 1.41 Kgf), P7 to P8 (2.75 ± 0.35 to 3.5 ± 0.00 Kgf). Formulation P9 that contained 0% binder had hardness value of 1.75 ± 0.35 Kgf. Increase in binder concentration results in increase in particulate bonding, which leads to increase in tablet hardness. At a given binder concentration (2%), paracetamol tablets formulated with *Sida acuta* gum as the binder produced the highest hardness value (6.75 ± 0.35 Kgf), followed by starch mucilage (4.0 ± 1.41 Kgf) and then HPMC (3.5 ± 0.00 Kgf). This showed that *Sida acuta* gum has the highest binding capacity among the three gums used.

Tablet friability

The friability of tablets from formulations P1 to P9, as shown on Table 3, was between 0.09 and 3.18. They were all below 1 % except P9 and N9. This indicates that they can withstand abrasion during further handling and transportation. Formulations P9 did not contain any binder and that may explain its high friability value. It was noticed that friability also decreased as the concentration of the binder in the formulation increased. Increase in binder concentration results in increase in intra-granular force or cohesion and consequently lower rate of chipping on abrasion. This was in agreement with the reports of previous researchers.[21, 22, 23]

Weight variation

The B.P states that for tablets having weight of 250 mg or more, a limit of ±5% deviation from the mean of the twenty tablets used is allowed. The % weight deviation for Formulations P1 to P9 tablets ranged from 0.00 to 3.33%. They therefore conformed to the standard. Weight variation is caused by poor flow of granules, variation in size of granules due to improper sieving, presence of very fine granules, improper adjustment of machine and improper flow rate.

Disintegration time test

The disintegration time for tablets from formulation P1 to P9, were as shown on Table 3.

This shows that disintegration time increases (6.33 ± 5.86 to 49.00 ± 1.00 min) as the concentration of the binder (0.5 to 2 %) increases. Increase in binder concentration results in increase in cohesion between the particles, therefore more time is needed to separate the particles. At similar binder concentration (e.g. 2 %), the disintegration time for tablets formulated with *Sida acuta* as binder (49.00 ± 1.00 min) was more than that formulated with starch mucilage (1.53 ± 0.13 min) and HPMC (0.79 ± 0.41 min). Therefore, smaller quantity of *Sida acuta* gum than the other binders may be needed to produce tablets having a given disintegration time. This is an economic advantage for *Sida acuta* gum.

Drug content

The drug content of the formulations was found to be between 97.2 to102% for P1 to P9. The values signified good uniformity of the drug content in the tablets. Proper powder mixing and good powder or granule flow from the hopper to the die of the tableting machine ensures adequate drug content.

Table 3: Tablet evaluation of formulations P 1 to P 9,

FORMULATIONS	P 1	P 2	P 3	P 4	P 5	P 6	P 7	P 8	P 9
WEIGHT (g)	0.60± 0.02	0.59± 0.03	0.59± 0.00	0.60± 0.02	0.60 ± 0.00	0.59± 0.00	0.59± 0.00	0.59± 0.01	0.59± 0.03
HARDNESS (Kgf)	3.5 ± 0.00	5.0 ± 0.00	6.0 ± 0.00	6.75 ± 0.35	3.75 ± 0.35	4.0 ± 1.41	2.75 ± 0.35	3.5 ± 0.00	1.75 ± 0.35
THICKNESS (mm)	3.59± 0.18	3.38± 0.15	3.47± O.18	3.61± 0.26	4.01± 0.19	3.34± 0.03	3.46± 0.22	3.37± 0.06	3.85± 0.II
DIAMETER (mm)	12.93± 0.04	12.88± 0.04	13.13± 0.11	12.93± 0.04	13.08± 0.18	12.74± 0.00	12.95± 0.06	12.93± 0.04	13.15± 0.00
FRIABILITY	0.19	0.16	0.09	0.28	0.21	0.16	0.32	0.24	3.18
DISINTEGRATION TIME (min)	6.33 ± 5.86	9.83 ± 6.53	30.33 ± 13.65	49.00 ± 1.00	1.39 ± 0.10	1.53 ± 0.13	0.49 ± 0.08	0.79 ± 0.04	0.50 ± 0.00
DRUG CONTENT (%)	99.00	101.05	100.50	97.20	99.50	102.0	98.75	101.20	99.70

In vitro drug release studies

As shown in Figure 1, the percentage of paracetamol that was released from formulations P1 to P9 after 10 min was from 74.25% (P1) to 100% (P5) and after 45 min was 98.18% for P2 and 100 % for others. This was in accord with the results obtained for disintegration time test where tablets from all the formulations disintegrated within 10 min but for P3 (30 min) and

P4 (49 min). All the formulations released more than 75 % of their drug contents within 45 min and therefore they all passed the dissolution test.

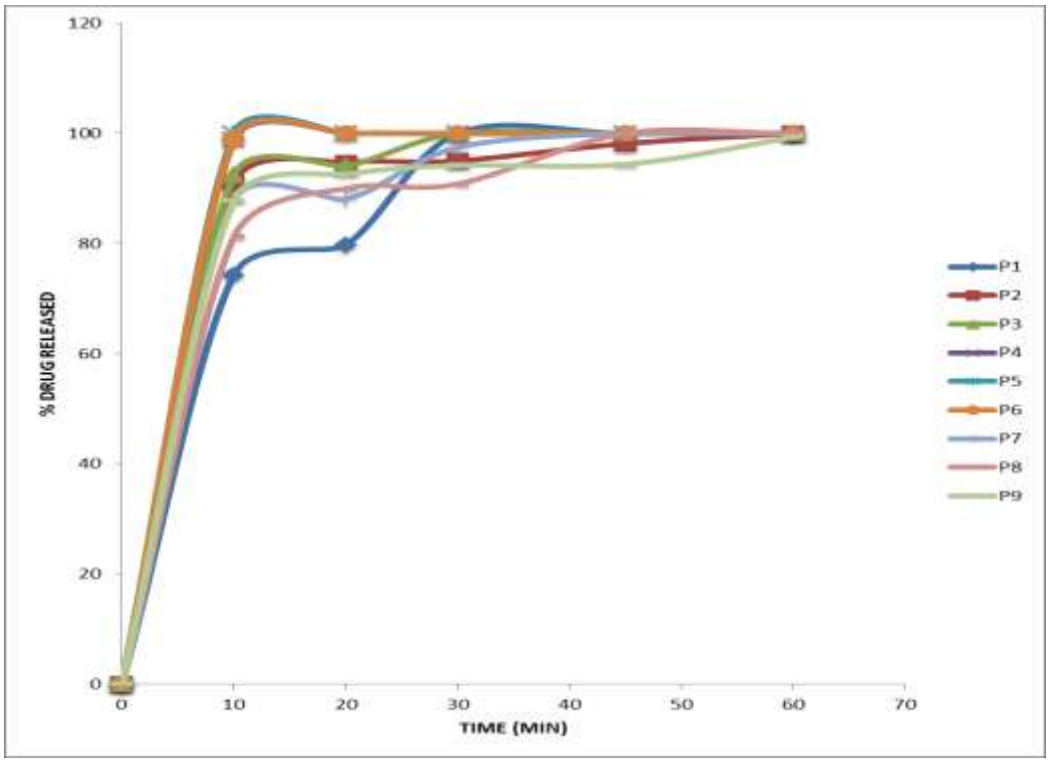

Fig. 1: In vitro drug release profile of paracetamol from formulations P 1 – P 9 tablets,

Key: P1 = SAG (0.5%), P2 = SAG (1%), P3 = SAG (1.5%), P4 = SAG (2%), P5 = Starch mucilage (1.5%), P6 = Starch mucilage (2%), P7 = HPMC (1.5%), P8 = HPMC (2%), P9 = 0 % binder

Stability of paracetamol tablets

As shown on Table 4, the result of analysis done on paracetamol tablets from formulation P1 after 6 and 12 months did not show any significant difference ($p \leq 0.05$) from that done on the first day of analysis. Tablet hardness test, friability test, disintegration time test, in – vitro dissolution test and drug content analysis all indicated that the tablets maintained both physical and chemical stability after the period of storage.

Table 4: Tablet evaluation for paracetamol after storage for one year.

FORMULATION	PARACETAMOL (P1)		
TIME (MONTHS)	0	6	12
HARDNESS (kgf)	3.59 ± 0.18	3.70 ± 2.6	4.01 ± 1.80
FRIABILITY (%)	0.19	0.2	0.2
DIS INTEGRATION TIME (MIN)	6.33 ± 5.86	6.35 ± 2.90	6.40 ± 3.50
DRUG CONTENT (%)	99	99	98.95

CONCLUSION

Sida acuta gum was used as a binder in concentrations as low as 0.5 - 2% w/w, in the formulation of paracetamol tablets. The tablets formulated using 0.5 - 1% w/w concentrations, passed disintegration time, hardness and friability tests. It has higher binding capacity than starch mucilage and HPMC when used as a binder in paracetamol tablets at the same concentration.

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