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ORIGINAL RESEARCH ARTICLE

Comparative Study of Binding Potency of Different Starches in Tablet Formulation

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ABSTARCT

This study was carried out to compare the binding effects of rice, potato, banana and tapioca starches which were isolated. Granule properties such as angle of repose, bulk and tapped Hausner's ratio, Carr's index and tablet properties which included weight uniformity, friability, disintegration times, and dissolution rates using standard methods. Mucilages of the starches of varying concentrations of 2, 4, 6 and 8%w/v were used to produce Paracetamol granules by wet granulation method and compressed into tablets. An increase in binder concentration led to an increase in crushing strength, decrease in friability and increase in disintegration time of the tablets. Tapioca starch produced the hardest tablets and also the least friable tablets, the longest disintegration time and dissolution time when compared to potato, banana and tapioca starches.

Key words: Binding effect, hardness, starch, wet granulation.

INTRODUCTION

Starch is one of the most widely used excipients in the manufacture of solid dosage forms. Starches from different sources have been evaluated and used as excellent binders in either mucilage or the dry powdered form. Although maize starch is the most frequently used excipient in tableting, researchers have tried to develop botanical starches for use tablet excipients. Preliminary evaluation of these starches following official and unofficial protocols showed that they possess some of the desirable features of good excipients [1].Nasipuri (1979) evaluated the use of *Dioscorea rotundata* as a binder and disintegrant in tablet formulation and Itiola also investigated the compressional properties of this particular starch[3]. The effects of pigeon pea and plantain starches on the compressional, mechanical and disintegration properties of Paracetamol tablets have been investigated [4]. Ibezim *et al.* (2008) have also investigated the role of ginger starch as binder in acetaminophen tablets. Binders are agents employed to impart cohesiveness to the granules. This ensures the tablet remains intact after compression as well as improving the flow qualities by the formulation of granules of derived hardness and size. 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 [6]. This study investigated the effect of the nature of two starches as binders on physical properties of paracetamol tablets using the massing and screening method of wet granulation. Paracetamol was chosen for the work as a model drug.

MATERIALS AND METHODS

MATERIALS

The following materials were used as obtained from the manufacturers without further purification. The experimental starches (rice, banana, tapioca) were prepared in a laboratory in Swami Vivekanand College of pharmacy. Sodium Hydroxide, Hydrochloric Acid, acetic acid, methanol AR (SDFCL), lactose, talc, magnesium stearate and PVP (HIMEDIA).

METHODS

Extraction of Rice, banana and tapioca starches [1] [9]

1) Rice starch:

Broken pieces of rice were soaked in 0>4% aqueous solution of NaOH then insoluble protein, gluten dissolved and grains Softened by the soaking, diluted suspension is centrifuged to

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separate starch by centrifuge apparatus, and isolated starch was dried at 60^0Cfor 3 days.

2) Banana starch:

Green bananas are cut in to small pieces and milled in to make paste immerse this paste in to vegetable steamer for 2 hrs then cooled up to 30^0 C for 1 hr. then the solid material is filtered from mush and starch is dried at 60^0 C for 3 days.

3) Tapioca starch:

Tubers of cassava were peeled, washed and cut in to small pieces then these pieces were soaked with water for 1-2 hrs then this slurry was diluted with water and sieved with 100µ mesh size sieve, this process was repeated for 3 times and then starch was isolated from solution and dried at 60^0 C for 3 days.

Formulation of paracetamol granules and tablets [7]:

Paracetamol granules containing 71.4 mg Paracetamol were prepared with rice starch, banana starch, tapioca starch and potato starch as binders in four different formulation of each starch which contains 2%, 4%, 6% and 8% of starch, 2.5% PVP is used as disintegrant 0.2%Talc is used as glidant and 0.2% Magnesium stearate as lubricants. The wet granulation method was employed in the formulation of the tablets. The required quantities of paracetamol and disintegrant were weighed and mixed with the binder mucilage (wheat, rice and maize starch BP). The resulting wet masses were screened by passing them manually through a 1700 µm mesh size and dried for 20minutes at 40ºC in the oven and then screened through the 1600 µm and then dried to constant weight in the oven. The granules were then mixed with the required quantities of lubricants and then compressed into tablets.

PRECOMPRESSION PARAMETERS OF GRANULES:

1. Angle of repose:

Fifty grams (50 g) of the granules was placed in a plugged glass funnel which had a distance of 10cm from the flat surface. The granules were then allowed to flow through the funnel orifice by removing the cotton plug from the funnel orifice. The height of the heap (*h*) formed as well as the radius of the heap (*r*) was noted. The angle of repose (*Q*) was calculated as:

$$Q = \tan^{-1}\frac{h}{r}$$

2. Bulk and Tapped densities:

Thirty grams (30 g) of the granules were carefully poured through a short stemmed glass funnel into a 100ml graduated cylinder. The volume occupied by the granules was read and the bulk density calculated in gm/ml. The cylinder containing the granules was tapped fifty times from a height of 2cm and the tapped density calculated in gm/ml.

3. Percentage compressibility (Carr's index) and Hausner's ratio:

The percentage compressibility (*CI*) was calculated from the difference between the tapped densities (*Dt*) and the bulk densities (*Bt*) divided by the tapped densities. The Hausner's ratio (*HR*) is the ratio between the tapped and bulk density.

$$CI = \frac{Dt - Bt}{Dt} \times 100$$

$$HR = \frac{Dt}{Bt}$$

POSTCOMPRESSION EVALUATION OF TABLETS [5]:

1. Tablet thickness:

The thickness of ten tablets each selected at random from the formulated batches was determined using a vernier calliper and the mean of these readings was taken as the mean tablet thickness.

2. Tablet weight uniformity:

Twenty (20) tablets were weighed individually on the Mettler electric balance (P163 Mettler instrument AG) from which the mean was calculated and the percentage deviations determined.

3. Hardness:

The crushing strengths of the tablets were determined individually with the Monsanto hardness tester, following (Brook and Marsha, 1968). Ten (10) tablets were used and the mean crushing strength was calculated.

4. Friability:

The friability of the tablets was determined using the Erw eka friabilator Type A3R. Ten (10) tablets were weighed and put into the Erweka Friabilator and set to rotate at 25 rounds per minute for about four (4) minutes. The tablets were then removed and weighed again.

5. Disintegration test:

Six (6) tablets were placed in each compartment of the Erweka disintegration apparatus, with water thermo stated at 37 ± 0.50C as the medium. The tablets were considered to have passed the test after the six (6) tablets passed through the mesh of the apparatus in 15 minutes.

6 IN-Vitro drug release study:

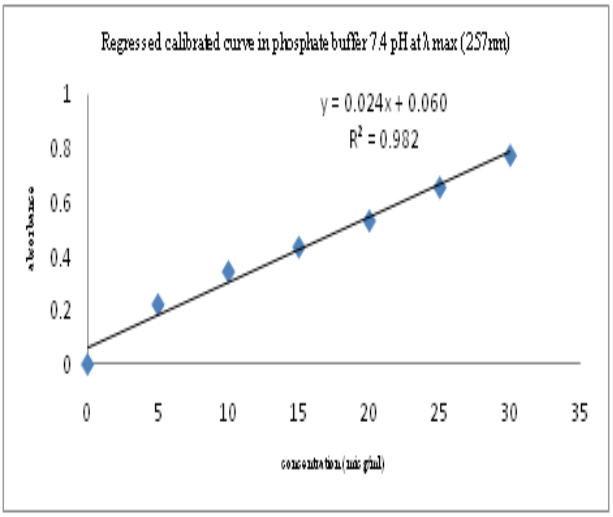
Weigh and powder 20 tablets. Weigh accurately a quantity of the powder equivalent to about 0.15 g

of Paracetamol, add 50 ml of 0.1M sodium hydroxide, dilute with 100 ml of *water*, shake for 15 minutes and add sufficient water to produce 200.0 ml. Mix, filter and dilute 10.0 ml of the filtrate to 100.0 ml with water. To 10.0 ml of the resulting solution add 10 ml of *0.*1M sodium hydroxide, dilute to 100.0 ml with water and mix. Measure the absorbance of the resulting solution at the maximum at about 257 nm and amount of drug was calculated.

7. Calibration curve for paracetamol:

A stock solution of 100mg of paracetamol was dissolved in 100ml of phosphate buffer 7.8 pH. Various dilutions of the stock were made and the absorbances of the various dilutions were taken at 357nm using a UV spectrophotometer. A plot of the absorbance, A against concentration, C was made and the calibration curve was determined from the slope of the graph.

Fig 1: Calibration curve for paracetamol



RESULTS FOR EVALUATION OF GRANULES:

1. Physicochemical characterization of formulation F_1:

Table 1: Physicochemical characterization of formulation F_1

S. No	Starch	Bulk Density P_b (gm/cm^2)	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	0.94	0.78	17	1.20	24.5
2	Potato	1.06	0.82	22.6	1.29	26.7
3	Banana	0.85	0.63	25.8	1.34	22.8
4	Tapioca	0.89	0.71	20.2	1.25	20.9

2. Physicochemical characterization of formulation F_2:

Table 2: Physicochemical characterization of formulation F_2

S. No	Starch	Bulk Density P_b (gm/cm^2)	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	0.94	0.78	17	1.20	24.5
2	Potato	1.06	0.82	22.6	1.29	26.7
3	Banana	0.85	0.63	25.8	1.34	22.8
4	Tapioca	0.89	0.71	20.2	1.25	20.9

3. Physicochemical characterization of formulation F_3:

Table 3: Physicochemical characterization of formulation F_3

S. No	Starch	Bulk Density P_b (gm/cm^2)	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	0.99	0.81	18	1.22	24
2	Potato	1.09	0.85	22	1.28	26.1
3	Banana	0.88	0.68	22.7	1.29	22.1
4	Tapioca	0.94	0.74	21.2	1.27	21.3

4. Physicochemical characterization of formulation F_4:

Table 4: Physicochemical characterization of formulation F_1

S. No	Starch	Bulk Density P_b (gm/cm^2)	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	0.99	0.81	18	1.22	24
2	Potato	1.09	0.85	22	1.28	26.1
3	Banana	0.88	0.68	22.7	1.29	22.1
4	Tapioca	0.94	0.74	21.2	1.27	21.3

POST COMPRESSION PRARMETER OF TABLETS:

1. Post compression evaluation parameter of formulation F_1:

Table 5: Post compression evaluation parameter of formulation F_1

S. No	Starch	Bulk Density P_b (gm/cm^2)	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	1.02	0.83	18.6	1.18	25.1
2	Potato	1.12	0.88	21.4	1.27	26.9
3	Banana	0.96	0.70	27	1.37	22.3
4	Tapioca	0.97	0.77	20.6	1.25	21.5

2. Post compression evaluation parameter of formulation F_2:

Table 6: Post compression evaluation parameter of formulation F_2

S. No	Starch	Bulk Density P_b (gm/cm^2)	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	1.02	0.83	18.6	1.18	25.1
2	Potato	1.12	0.88	21.4	1.27	26.9
3	Banana	0.96	0.70	27	1.37	22.3
4	Tapioca	0.97	0.77	20.6	1.25	21.5

3. Post compression evaluation parameter of formulation F_3:

Table 7: Post compression evaluation parameter of formulation F_3

S. No	Starch	Bulk Density P_b(gm/cm ^{2})	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	1.02	0.83	18.6	1.18	25.1
2	Potato	1.12	0.88	21.4	1.27	26.9
3	Banana	0.96	0.70	27	1.37	22.3
4	Tapioca	0.97	0.77	20.6	1.25	21.5

4. Post compression evaluation parameter of formulation F_4:

Table 8: Post compression evaluation parameter of formulation F_4

S. No	Starch	Bulk Density P_b (gm/cm^2)	Tapped density P_t(gm/cm^2)	C.I. (%)	Hausner ratio	Angle of repose (Θ)
1	Rice	1.02	0.83	18.6	1.18	25.1
2	Potato	1.12	0.88	21.4	1.27	26.9
3	Banana	0.96	0.70	27	1.37	22.3
4	Tapioca	0.97	0.77	20.6	1.25	21.5

Bulk and tapped density of the granules was significantly increased with increasing concentration of starch and the good correlation was observed between the concentration of binder and the density. The bulk and tapped densities (0.63-1.02 gm/cm^2) exhibited by banana and tapioca starch granules lower as compare to that of rice and potato starch granules (0.78-1.15 gm/cm^2).

Angle of repose gives a qualitative assessment of internal and cohesive friction forces. An angle less than 30^0 indicates good flow potential. All starches of granules showed an angle of repose less 30^0 and were therefore classified as material with good flow potential.

A Carr's Index of less than 15% indicates an adequate flow of granules and stable packing while values of more than 25% are characteristic of poor flow property all formulations shows Carr's Index more than 15% which shows poor flow property. Hausner ratio may be related to the compressibility of powder and value of more than 1.2 are indicative of passable compressibility here all formulation shows Hausner ratio more than 1.2 which shows poor compressibility.

Tablet thickness is varying with compressional force and density of granules. The tablet thickness of all the formulation is found (0.210-0.220cm) which may be attributed to their similar bulk and tapped densities and same compressional force used.

Tablet hardness is observed higher (3.15-3.95 kg/cm^2) with tapioca starch at all the concentration employed compared to those of rice, potato and banana starch which may be due to higher compaction power and good binding potency of these starches.

Disintegration time (10.46- 15.25min) is observed to be higher with tapioca starch at all the concentration employed compared to those of rice, potato and banana starch which may be due to higher compaction power and good binding potency of these starches.

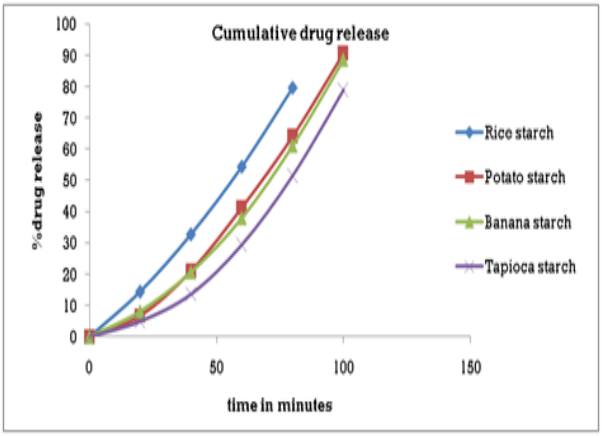
Friability is another mechanical property of a tablet with compendia l (USP 1995) specification not more than 1%. It was observed that paracetamol tablets prepared with potato banana and tapioca starch passes the friability test, for all the formulation and for rice starch only F_4 formulation passes the test.

The weight variation found in the range (2-4%) in case of all the formulation. All the batches prepared passed the weight variation test as per reported in USP.

IN-VITRO DRUG RELEASE STUDY

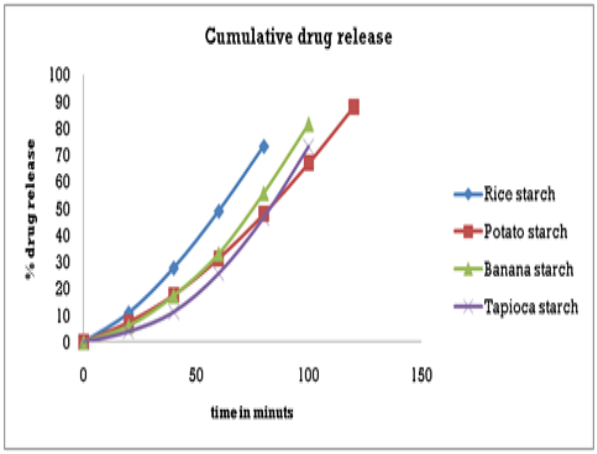
1. Cumulative drug release for tablet formulation F_1

Fig2: Percent cumulative drug release of formulation F_1 in Phosphate buffer of pH5.8



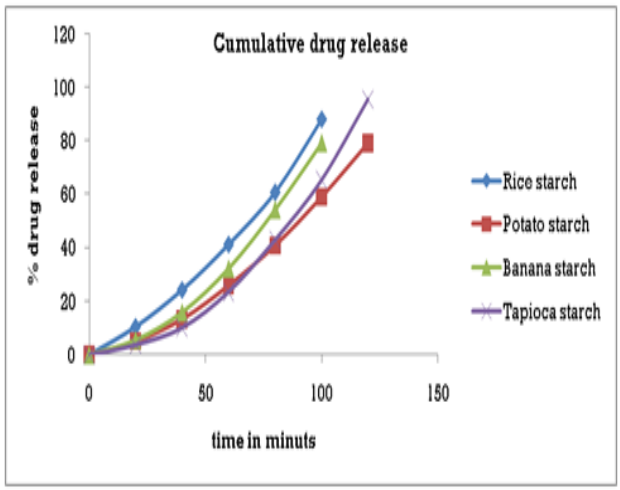
2. Cumulative drug release for tablet formulation F_2

Fig 3: Cumulative drug release for tablet formulation F_2 in Phosphate buffer of pH5.8



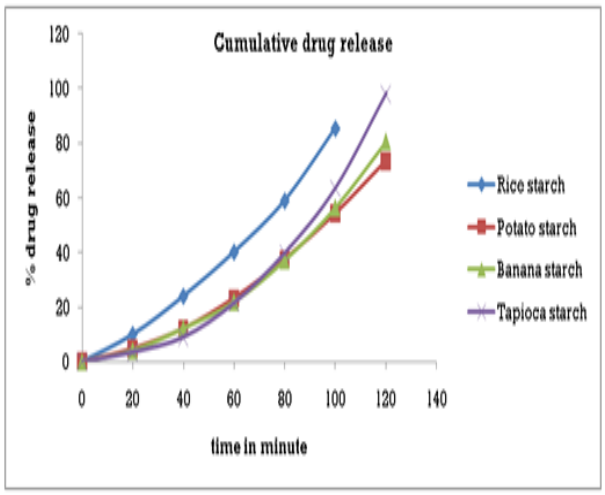
3. Cumulative drug release for tablet formulation F_3

Fig 4: Cumulative drug release for tablet formulation F_3 in Phosphate buffer of pH5.8



4. Cumulative drug release for tablet formulation F_4

Fig 5: Cumulative drug release for tablet formulation F_4 in Phosphate buffer of pH5.8



The result of in vitro drug release study shows that for F_1 and F_2 tablet formulated with tapioca starch shows slow drug release profile in comparison to other starch tablet. While in case of formulation F_2 and F_3 the slower drug release was observed with potato starch tablet. In all the formulation, the drug release rate decreased when the proportion of binder increased which may be due to increase in compaction force and greater degree of binding.

In all the formulation, the drug release rate decreased when the proportion of binder increased. It was reasoned that, as the amount of binder in the compact increased, there would be a greater degree of binding

Effect of tapioca starch on physicochemical property of tablet:

Table 6.1: Effect of concentration in physicochemical parameters of tablets of tapioca starch:

S. No	Formulation	Hardness (in kg/cm^2)	Friability	Disintegration time(in minutes)
1	F_1	3.15	0.96	10.46
2	F_2	3.25	0.92	12.25
3	F_3	3.5	0.80	15.25
4	F_4	3.95	0.73	15.55

Fig.6.5: Effect of conc. on hardness of tablet

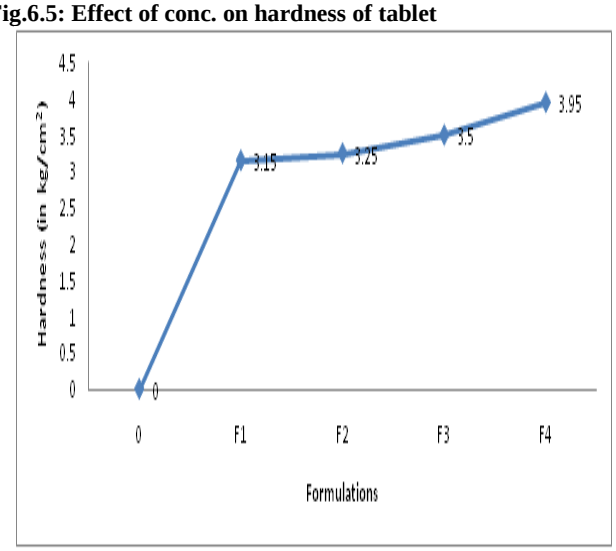


Fig.6.6: Effect of conc. on friability of tablet

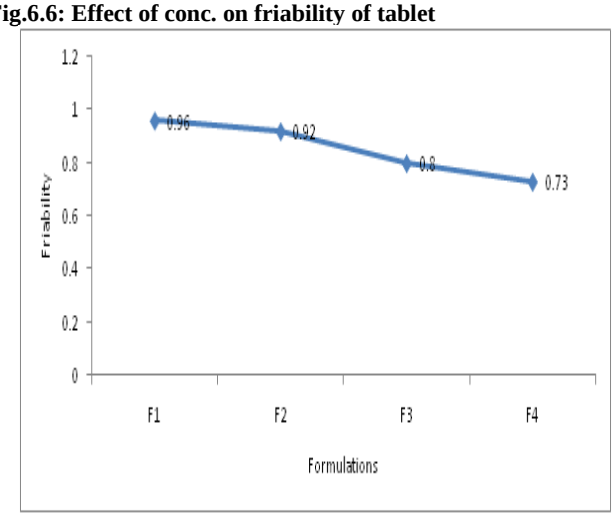
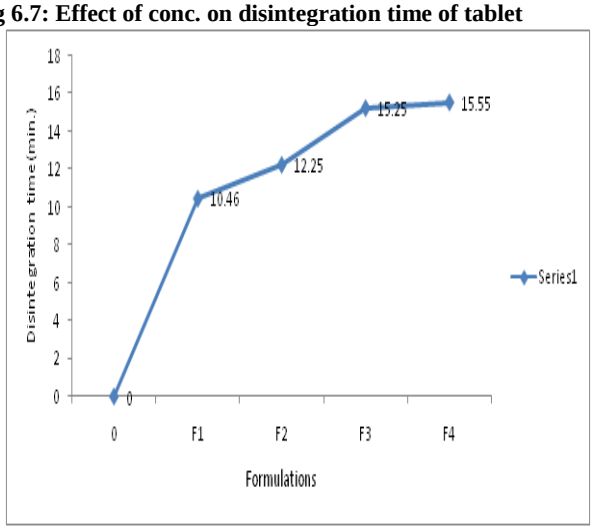


Fig 6.7: Effect of conc. on disintegration time of tablet



From the graph 6.5 and 6.7 it was found that increasing the concentration of tapioca starch there is significant increase in hardness and disintegration of the tablets. The correlation between the concentration of tapioca starch and hardness and disintegration time of the tablet is positive. From the graph 6.6, friability is found to be negatively correlated with concentration of tapioca starch as the concentration increases the friability decreases. The observation shows that tapioca starch has good binding potency.

CONCLUSION

It has been concluded from the results in this study that the tablet formulated with tapioca starch will have good effects on the friability, hardness, disintegration time and percentage of drug release from the tablets produced. Tablet formulated with tapioca starch are less friabable, harder, shows longer time for disintegration and good drug release profile in comparison to tablets formulated with rice, potato and banana starch. The percentage of drug release shows that the tapioca starch had a great influence on binding strength of the tablet. If this could be proved in a large scale, then it is very much beneficial to the tablet manufacturing industry as it is cheap and abundantly available.

REFRENCES

1. Alebiowu, G.Steeping period influence on physical, compressional and mechanical properties of tapioca starch J, Pharm. Res, 2007, 6, 139-144.
2. Ibezim EC, Ofoefule SI, Omeje EO, Onyishi V I and Odoh UE, The role of Ginger starch as a binder in Acetaminophen tablets, Sci. R es. Essay, 2008, 3, 46-50.
3. Itiola, OA, Odeniyi MA and OA, Adetunji.Compression, mechanical and release properties of chloroquine phosphate tablets containing corn and trifoliate yam starches as binders, Trop. J. Pharm. Res., 2006, 5, 589-96.
4. Kunle OO, Akin-Ajani DO, Odeku, OA, Itiola OA and Odusote OM, Effects of pigeon pea and plantain starches on the compressional, mechanical, and disintegration properties of paracetamol tablets, Drug Dev. Ind. Pharm., 2006, 32, 357- 365.
5. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy. Bombay: Varghese Publishing House, 1987, 3rd ed, 371-76.
6. Mattsson, S, Pharmaceutical binders and their function in directly compressed tablets, mechanistic studies on the effect of dry binders on mechanical strength, pore structure and disintegration of tablets. Acta Universitatis U plesaliensis Uppsala, 2000, 238.
7. Ngwuluka NC, Idiakhoa BA, Nep EI, Ogaji I,Okafor I S. Formulation and evaluation of paracetamol tablets manufactured using the dried fruit of Phoenix dactylifera Linn as an excipient, Res. Pharm. Biotech.,2010, 2, 26-32.
8. Nasipuri RN, Evaluation of yam starch as tablet binder and disintegrant, Nig. J. Pharm., 1979, 10,162.
9. Wang L and Wang YJ. Rice starch isolation by neutral protease and high-intensity ultrasound. B.R. Wells Rice Research Studies. 2003; 415-9.