World Journal of Pharmaceutical Sciences
ISSN (Print): 2321-3310; ISSN (Online): 2321-3086
Published by Atom and Cell Publishers
Available online at: http://www.wjpsonline.org/
Original Article

Evaluation of native and modified starch dispersions in mucilage obtained from sweet potato in ascorbic acid chewable tablet formulations

Achor M[*1], Allagh T.S[2], Hassan M[2] and Isah A. B[2]

[1]Faculty of Pharmaceutical Sciences, Usmanu Danfodiyo University, Sokoto, Nigeria
[2]Faculty of Pharmaceutical Sciences, Ahmadu Bello University, Zaria, Nigeria

Received: 26-11-2014 / Revised: 11-02-2015 / Accepted: 15-02-2015

ABSTRACT

Increasing attention has been paid in incorporating hydrocolloids into starch-based products due to their unique functional properties and bio-safety. The aim of this work was to evaluation native and modified starch dispersions in mucilage obtained from sweet potato in ascorbic acid chewable tablet formulation. Native starch and mucilage were extracted from sweet potato. Subsequently, native starch was pregelatinized and dispersions of mucilage with native and pregelatinized starches in a ratio 3:10 were produced. Ascorbic acid chewable tablets were formulated using these excipients and characterized based on their disintegration time, crushing strength, friability, dissolution time and panel assessment. All ascorbic acid chewable tablets made from starch dispersions were round and brown in colour with a characteristic sweet potato flavour. Generally, there was a significant difference in disintegration time, crushing strength, friability, dissolution time and panel assessment between formulations made with dispersion of native and modified starch. Formulation F7 – F9 which contains maltitol and Avicel HFE had the highest cumulative drug release (≥ 100 %) within 15 min. Formulations F1 – F2 which contains native and modified starch dispersions alone had a better degree of acceptance as compared to formulations with maltitol and Avicel HFE.

Key word: Sweet potato, pregelatinized starch, mucilage, dispersion

INTRODUCTION

Starch and mucilage are most commonly used as adjuvant in pharmaceutical preparations, with wide range of applications. In recent years, plant derived polymers have evoked tremendous interest due to their diverse pharmaceutical applications such as diluent, binder, disintegrant in tablets, thickeners in oral liquids, protective colloids in suspensions, gelling agents in gels and bases in suppository [1]. These polymers such as natural gums and mucilage are biocompatible, cheap and easily available and are preferred to semi-synthetic and synthetic excipients because of their lack of toxicity, low cost, availability, soothing action and non-irritant nature [2-3]. Approximately 80 g/100 g of root and tuber crops' dry matter is made up of carbohydrates, which consist mainly of starch, mucilage, and sugars [4]. Due to their high starch content, root and tuber crops play a significant role in manufacturing, and are also used as ingredients of fabricated foods and pharmaceuticals around the world. Increasing attention has been paid to incorporating hydrocolloids into starch-based products due to their unique functional properties. Polysaccharide hydrocolloids including mucilage's, gums and glucans are abundant in nature and are commonly found in many higher plants. Blending of starches with other biopolymers is a well-known technique to modify texture or maintain desirable texture during long storage period [5-6]. Pregelatinized starch is a starch that have been chemically and/or mechanically processed to rupture all or part of the starch granules. In comparison to starch, partially pregelatinized starch may be produced with enhanced flow and compression characteristics such that the pregelatinized material may be used as a tablet binder in dry compression or direct compression processes [7].

Recent developments in dosage form technology (especially chewable tablets) are concentrating on presenting the patient with viable dosage alternatives which provide good palatability and ease of administration at the same time. This is especially valid when the preparation is to be administered to an infant or to an elderly patient.

***Corresponding Author Address:** Achor, M, Faculty of Pharmaceutical Sciences, Usmanu Danfodiyo University, Sokoto, Nigeria; E-mail: munchors001@yahoo.com*

However, the presence of mucilage in tuber crops itself, has received little attention, particularly the effects of mucilage on the material properties of extracted starches in relation to tablet production. In view of the fact that sweet potato mucilage can be used to enhance food product through colour, flavor, natural sweetness and supplemented nutrients, the objective of this study is to evaluation modified starch and mucilage dispersion obtained from sweet potato in ascorbic acid chewable tablet formulation.

MATERIALS AND METHOD

Materials: Sweet potato (white skin, cream flesh variety) was obtained from central market in Sokoto State, Nigeria. All other chemicals and reagents used were of analytical grade.

Methods

Flour Extraction: Flour extraction was conducted as established by Alves [8]. The tubers were peeled, washed, cut into 1-2 cm cubes, and sliced into thick chips (~5mm). This chip was then soaked in sodium metabisulphite solution (0.075 %) for ~5 min and oven dried at 30 ^{0}C for 40 h until it reached 13 % moisture. Subsequently, the dried chips were milled (PZ, Barnerx Chem Ltd. England) into flour and sifted through a 500 µm sieve (BS), and stored under dry conditions at room temperature.

Mucilage Separation: The mucilage concentrate was prepared following the method described by Achor [9]. Flour sample (100 g) was dispersed in 300 ml of sodium metabisulphite (0.075 %) solution and stored at 4 ^{0}C overnight. This dispersion was centrifuged (TDL-4, Zhejiang, China) at 14,000 x g for 20 min and the supernatant (mucilage) collected. This was followed by pellet dissolution in metabisulphite solution and centrifuged as described before. The resulting supernatant was filtered using a filter paper (110 mm diameter) and purified as follows: 150 ml of the supernatant was treated with 0.5 % saturated solution of calcium chloride and left overnight. Subsequently, the supernatant was carefully collected and further treated by heating (DKZ-2, Uniscope, Shangai, China) at 95 ^{o}C for 30 min and allowed to cool to room temperature. The resulting supernatant was precipitated using three times its volume of ethanol (96 %) and then dried in an oven (FN-055, Nuve, Turkey) 40 ^{0}C.

Starch Isolation: The pellets obtained from the centrifugation step during the mucilage separation was re-suspended in 500 ml of sodium metabisulphite (0.075 %) solution, homogenated and passed through a 150 µm sieve. The residue was washed with sodium metabisulphite (0.075 %). The resulting slurry was left to stand overnight at 4 ^{0}C and then centrifuged (14,000 x g; 20 min). The supernatant was discarded and the colored layer manually scraped off of the starch. This centrifugation step was repeated until the supernatant layer becomes almost colorless. After the last centrifugation, the supernatant was decanted and 10 ml sodium hydroxide solution (0.1 M) added to the remaining sediment (starch). This was followed by addition of deionized water to wash the pellets until its pH became neutral. The recovered starch was dried using an air oven at 40 ^{o}C for 30 h, ground, and sieved using a 500 µm sieve. The yield of starch based on the weight of its respective flour (100 g) was determined. The resulting starch was stored in an air tight container under dry conditions**.**

Modification of Starch

Pregelatinization: In the production of partially pregelatinized starch, native starch 39.6 g was added to 70 ml of distilled water and the suspension stirred for 10 min at room temperature. The suspension was heated on a water bath (DKZ-2, Uniscope, Shangai, China) thermostatically maintained at a temperature of 55 ^{0}C (i.e. below the gelatinization temperature) for 15 min, the resultant paste was dried in a hot air oven at temperature of 40 ^{0}C to a moisture content of <10 %, then ground into a powder and passed through a 500 µm sieve.

Starch and Mucilage Dispersions: Production of mucilage/native starch (MSPS) and mucilage/pregelatinized starch (MPPS) dispersions in a ratio 3~~0~~:10~~0~~ were carried out as follows: sweet potato mucilage was slowly added to distilled water (150 ml) with stirring until dissolution was effected. Starch (native and pregelatinized) was then added to the mucilage solutions, and the dispersion stirred for one hour at room temperature. The whole dispersion was then transferred into a glass dish and dried at 45 ^{0}C in an oven to a moisture content of < 10 %, milled and passed through a 500 µm sieve.

Compatibility Studies: Fourier transform infra red (FT-IR) spectra matching approach was used for detection of any possible chemical interaction between the starch and mucilage dispersion and ascorbic acid. A 1 mg quantity of the individual and physical mixture (1:1) of drug and mucilage powder was prepared and mixed with 49 mg potassium bromide. The mixture (50 mg) was compressed to form a transparent pellet using a hydraulic press at 5 tons pressure, and then scanned from 4000 – 400 cm^{-1} in a FTIR spectrophotometer (FT-IR, Nexus, USA). The IR spectrum of the physical mixture was compared with those of pure

ascorbic acid and matching done to detect any appearance or disappearance of peak.

Crushing Strength: Five tablets were taken and the crushing strength was determined using tablet hardness tester (YD-2, Vanguard Pharmaceutical Machinery INC, UK). Each tablet is placed between two anvils and the force that just causes the tablet to break was recorded. Crushing strengths recorded are averages of five tablets.

Friability Determination: Ten tablets from each batch were weighed and placed in the friability tester (Erweka TA3R friabilator, Erweka apparatebau GmbH, Western Germany) and subjected to combined effects of abrasion and shock. The apparatus was set to revolve at 25 rpm for 4 min. The tablets were dusted and weighed. The percent loss in weight was calculated as friability.

Disintegration Time (DT): DT test was carried out according to BP (2010) specification, six tablets were placed in a disintegration tester (Disintegration machine 78X Shanghai, China) filled with distilled water at 37 ± 0.2 ^{0}C. The tablets were considered completely disintegrated when all the particles passed through the wire mesh. Disintegration times recorded are mean of six determinations.

Dissolution Test: The dissolution test of ascorbic acid tablets were carried out according to the USP (2010) specification using dissolution apparatus Type II (Variant VK 7000 Dissolution Apparatus, NC, USA), with 900 ml of 0.1 N HCl as the dissolution medium at 37 ± 0.5 ^{o}C which was stirred at a rate of 100 rpm. Ascorbic acid was determined using spectrophotometer at wavelength of 244 nm.

Formulation of Ascorbic acid Chewable Tablets: Ascorbic acid chewable tablets were formulated by the direct compression method using single station tablet press (Manesty BB, Single Press Tableting Machine, UK) fitted with 8 mm punch and die assembly (batch size of 100 tablets) according to the following formulae (Table 1) at compression pressure of 6.0 metric tones

Panel Assessment Test: The sensory panel test was performed as follows; twenty volunteers, 20–24 years in age (both male and female), were selected to evaluate the taste of the chewable tablets. The volunteers were given the tablets to chew for 10 sec and then mouth rinsed out with water. Tablets were rated from 0 to 5 points for their appearance, aroma, hardness, taste, mouth feel sensation and aftertaste. The criteria for scoring were as follows: 1 = very poor, 2 = poor, 3 = acceptable, 4 = good and 5 = excellent. Overall tablets qualities were calculated as a sum of all recorded sensory properties.

RESULTS AND DISCUSSION

FT-IR spectra matching approach was used to detect any possible chemical interaction between ascorbic acid with MSPS and MPPS. Appearance or disappearance of peaks was used as an indication for interactions. As seen in Fig. 1 -2, there was no appearance or disappearance of peaks which indicate no interaction between ascorbic acid with MSPS and MPPS.

All tablets made from starch dispersions were brown in colour, round without any tablet defects and had a characteristic sweet potato flavor. All formulations had excellent friability; less than 1 %, crushing strength within 3.5 – 4.5 kgF and disintegration time less than 7 min. as seen in Fig. 3. Batches with Crosspovidone showed a significant higher crushing strength and lower disintegration time as compared to F1 and F2. This increase in crushing strength could be as a result of the highly compressible nature of Crosspovidone; due to their unique particle morphology and the lower disintegration time might be due to the super disintegration properties of Crosspovidone.

Formulation F5 – F8 had a decreased disintegration time and crushing strength due to the very soluble and the poorly compactable nature of sugar alcohols respectively. Ascorbic acid tablet made with Avicel HFE had friability of less than 1 %, better disintegration time as compared to other formulations and crushing strength above 4 kgf. Generally, there was a significant difference in friability, crushing strength and disintegration time between the dispersion of native and modified starch.

For the cummulative drug release (Fig. 4), formulation F9 which contains Avicel HFE had the fastest onset of drug release (69.75 %) as compared to formulation F1 –F2 (containing starch dispersions alone) which has the slowest onset of drug release (4.35 – 7.8 %). Generally, formulations F7 – F9 had the highest cumulative drug release (≥ 100 %) within 15 min.

For the panel assessment, tablets were rated from 0 – 5 points for their appearance, aroma, hardness, taste, mouth feel sensation and after taste. The overall tablet quality was calculated as the sum of all recorded sensory properties. All tablet formulations had acceptable appearance, aroma, hardness, taste, mouth feel and after taste which

were basically imparted by the starch dispersions without the addition of external colorant and flavoring agents except F9. This is evident because Sweet potato flour can be used to enhance food products through colour, flavor, natural sweetness and supplemented nutrients. Fig. 5 shows the degree of acceptance for the formulated chewable tablets. Formulation F3 had the highest acceptance while formulation F9 had the lowest. There was a significant difference at $p < 0.05$ between formulations F3 – F4 and other formulations. This could be as a result of sodium saccharine which imparted a higher response to taste. Formulations F1 – F2 which contains native and modified starch dispersions alone had a better degree of acceptance as compared to other formulations with maltitol and Avicel HFE.

CONCLUSION

Incorporation of mucilage into native and modified (pregelatinized) starch imparted a brownish, sweetened and characteristic sweet potato flavor to the respected starches. These dispersions possessed excellent properties as excipient for ascorbic acid chewable tablet formulations using the direct compression method in view of its physicochemical and tablet properties as well as its positive panel assessment.

Table 1: Formulae for Ascorbic Acid Chewable Tablets

Parameters (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ascorbic acid	100	100	100	100	100	100	100	100	100
MSPS	120	-	120	-	100	-	100	-	-
MPPS	-	120	-	120	-	100	-	100	-
Mannitol	-	-	-	-	20	20	-	-	-
Maltitol	-	-	-	-	-	-	20	20	-
Avicel HFE	-	-	-	-	-	-	-	-	120
Sodium saccharine	-	-	0.25	0.25	-	-	-	-	0.25
Crosspovidone	-	-	1.20	1.20	1.20	1.20	1.20	1.20	1.20
Magnesium stearate	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55

MSPS and MPPS represent 30 g of mucilage incorporated into 100 g of native and pregelatinized starch respectively

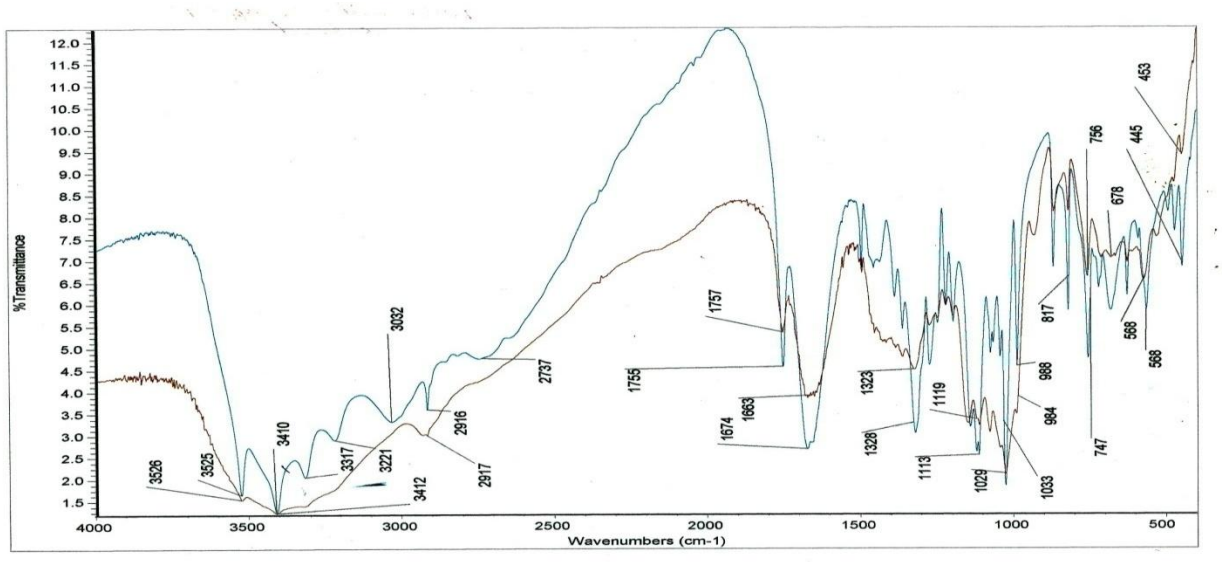

Fig. 1: FTIR Spectra of Ascorbic acid and MSPS

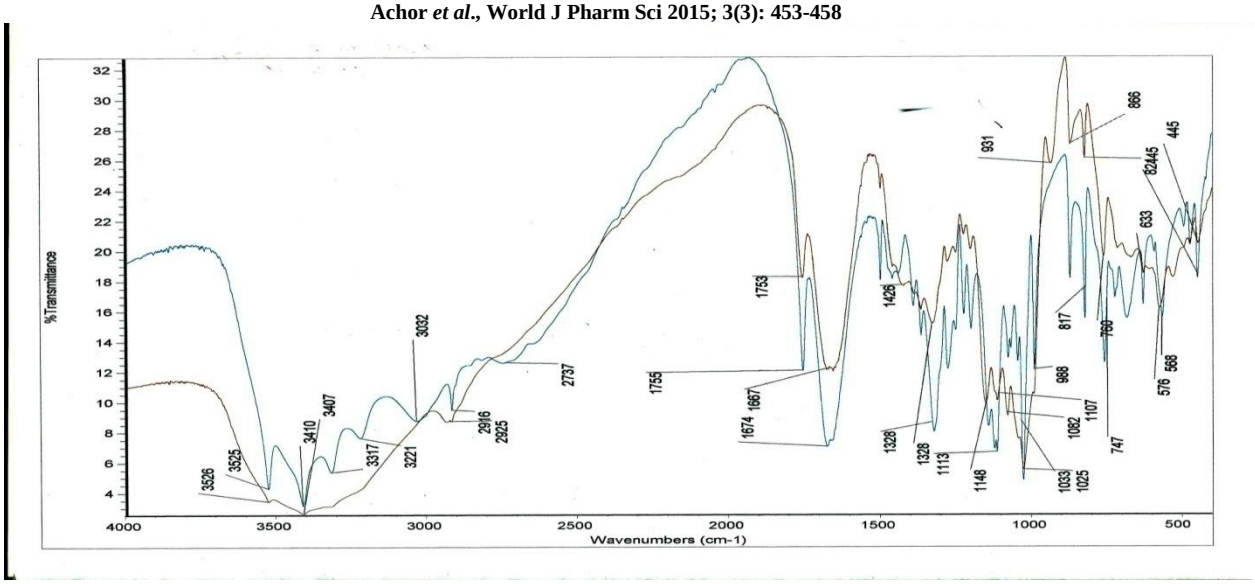

Fig. 2: FTIR Spectra of Ascorbic acid and MPPS

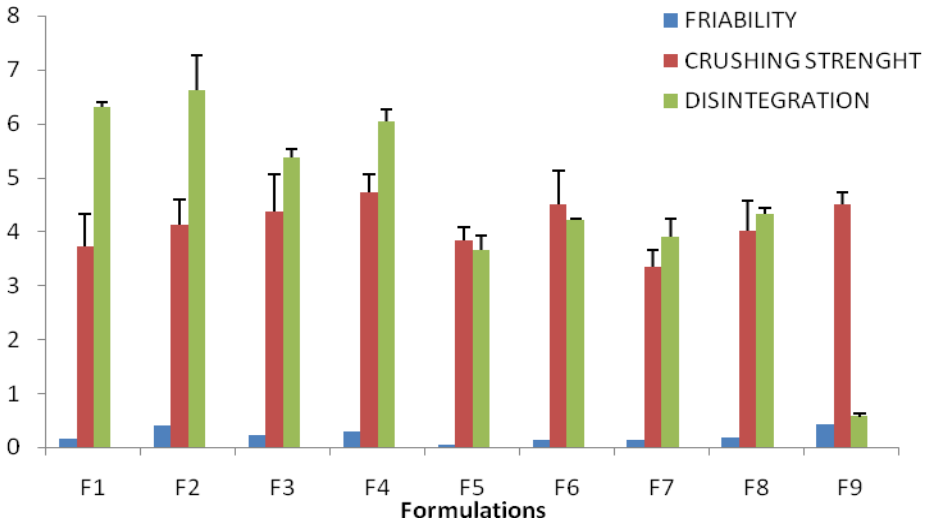

Fig. 3: Chart of Friability, Crushing Strength and Disintegration Time of Ascorbic acid Chewable Tablets

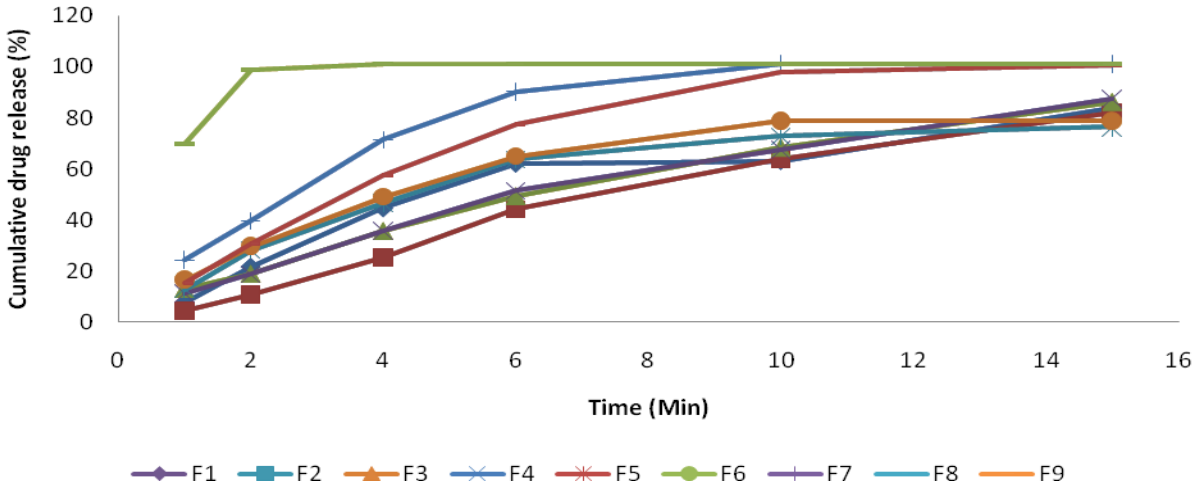

Fig. 4: Cumulative Drug Release for Optimized Ascorbic acid Chewable Tablet Formulations

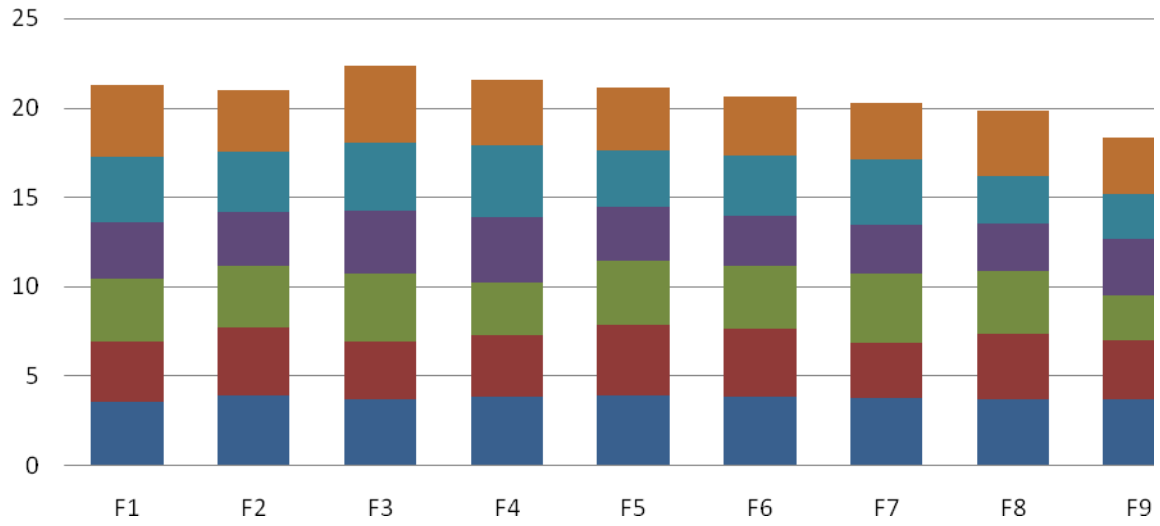

Fig. 5: Chart of Degree of Acceptance for Formulated Ascorbic acid Chewable Tablets

REFERENCE

1. Zatz JL, Kushla GP. Disperse systems. In: Reiger MM, Banker GS, eds. Pharmaceutical dosage forms. New York: Marcel Dekker Inc., 1989: pp 2: 508,
2. Whistler RL. In: Industrial gums, 2 Ed, Academic Press, London, 1996
3. Kulkarni GT et al. Development of controlled release spheriods using natural polysaccharide as release modifier, Drug Delivery 2005; 12: 201-206
4. Huang J et al. Physicochemical properties and amylopectin chain profiles of cowpea, chickpea and yellow pea starches, Food Chemistry 2007; 101: 1338-1345
5. Lee MH et al. Freeze-thaw stabilization of sweet potato starch gel by polysaccharide gums. Food Hydrocolloids 2002; 16 (4): 345-352
6. Tester RF, Sommerville MD. The effects of non-starch polysaccharides on the extent of gelatinization, swelling and alpha-amylase hydrolysis of maize and wheat starches. Food Hydrocolloids 2003; 17 (1): 41-54
7. Shiromani PK, Clair J. Statistical comparison of high-shear versus low-shear granulation using a common formulation. Drug Development and Industrial Pharmacy 2000; 26: 357-364
8. Alves RM et al. Chemical and functional characterization of products obtained from yam tubers. Starch 2002; 54: 476-481.
9. Achor M et al. Effect of Mucilage on the Physic-Chemical Properties of Native and Modified Starches obtained from *Ipomoea Batatas*. America Journal of Pharmtech Research 2014; 4 (3): 781 – 794