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EVALUATION OF THE DISINTEGRANT PROPERTIES OF CORN AND POTATO STARCHES IN IBUPROFEN TABLET FORMULATIONS

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ABSTRACT

Introduction: Disintegrants are non-active pharmaceutical agents that are added to tablet formulations to encourage their break-up into smaller fragments in an aqueous environment, resulting to an increased surface area thus, promoting a more rapid release of the active drug substance contained in the tablet for dissolution and absorption.
Aim: This study was aimed at evaluating the disintegrant properties of corn and potato starches in ibuprofen tablets
Method: The starches at 5 %w/w and 10 %w/w were applied as disintegrants in the formulation of ibuprofen tablets using wet granulation technique. The resultant granules were evaluated for their micromeritic properties and compressed into tablets. Evaluation of the ibuprofen tablets for their physical properties and dissolution studies were done using British Pharmacopoeia methods.
Results: The results obtained showed that ibuprofen granules were flowable and compressible. The compressed ibuprofen tablets had good physical properties: minimal weight variation (490 ± 0.01 – 500 mg ± 0.02), hardness (4.7 ± 0.03 – 6.3 ± 0.1 KgF), disintegration time (2.41 min ± 0.61 – 4.32 min ± 0.97) and friability (0.83 % ± 0.04 – 0.96 % ± 0.1). The dissolution of ibuprofen tablets complied with British Pharmacopoeia criteria.
Conclusion: Corn and potato starches served as good disintegrants in ibuprofen tablet formulations.
Keywords: Disintegrant, corn starch, potato starch, ibuprofen tablets.

INTRODUCTION

The pharmaceutical tablet ingested orally remains the most popular dosage form in drug delivery, and the most frequently used route for administration of therapeutic agents is the oral route[1]. The tablet dosage form has many advantages that makes it popular which includes accurate dosage administration of the drug, high level of therapeutic response, ease of self-medication which promotes a high degree of patient compliance and good shelf life of the product. The formulation of the pharmaceutical tablet is done with the active pharmaceutical ingredient (API) in combination with excipients that enhance the functionality of the dosage form. Conventional or immediate release tablet dosage forms are formulated in a manner that enhances the easy break up (disintegrate) of the tablet and release its API as soon as the tablet has been ingested and is resident in the stomach[5].

Much interest and attention has been geared towards the targeted drug delivery and

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

controlled release systems within the solid dosage forms, yet, the class of solid dosage forms which when ingested, break down to discharge their active pharmaceutical ingredients (API) instantly in the gastrointestinal tract have continued to enjoy much patronage[7].

Generally, tablets for disintegration constitute the most widely used among the pharmaceutical solid dosage formulas [4,6]. In a medicinal product formulation, the chances of absorption of the API especially the solid dosage form relies on its bioavailability which also depends on the solubility of the API in the gastrointestinal fluids as the drug crosses the intestines. The solubility of such API is influenced by the chemical conformation and physical form of the drug, the degree at which drugs go into solution in the physiological fluid is a function of the ease with which the tablet disintegrates. In immediate-release dosage forms, the disintegration process is specifically critical and for that reason, disintegrants are added to tablets to induce break-up when it comes in contact with the fluid [8]. A disintegrant is described as an inert substance which is added to a solid dosage formulation such as a tablet or capsule to enhance their break up to achieve the release and dissolution of the API by increasing the surface area of the tablet and softening the binding agent. This is so because when a tablet is exposed to an aqueous media, initially, it disintegrates into granules, and further into fine particles. This enhances the rate of dissolution in the media [10,13]. Most of the hydrophilic excipients which are soluble in water or gastrointestinal fluids serve as good disintegrants. Currently, cellulose-based materials and starch are utilized as disintegrants some of which are partially pregelatinized starches, low-substituted hydroxypropyl cellulose and microcrystalline cellulose. Disintegrants could be distinguished by their respective modes of action [9]. The most common mechanisms of action include exothermic wicking reaction, swelling of particles, particle deformation recovery, heat of interaction and particle repulsion. Swelling is often accepted as the key mechanism of tablet in disintegration. When a disintegrant swells, the adjoining ingredients are split up and initiate the crumbling of the tablet matrix. In wicking, the disintegrant eases the ability of the liquid to be drawn into the tablet matrix and initiating a break-up. Water penetration of the tablet is through the pores as well as along a hydrophilic complex by wicking of the disintegrant contained in the formulation [12, 14]. Incorporation of the disintegrant is done intragranularly, extragranularly or by both procedures especially in a wet granulation method of producing tablets [15,16].

Starch is a naturally occurring biomass material that is synthesized in most green plants which contains chlorophyll obtained from the process of photosynthesis [7]. Its storage in plants is not restricted to any part of the plant as it has been found to be widely distributed within the different parts of a plant such as the leaves of green plants, seeds, fruits, stems, roots, and tubers. However, the type of plant where starch synthesis takes place would greatly influence its level of distribution and storage within the plant. In the green leaves, starch is formed in the chloroplasts while in fruits and tubers, it is formed in the amyloplasts of seeds, fruits and tubers. However, in spite of the site of formation and storage in the plant, starch is consumed as food by animals, especially by man. Starch abounds in the grains of cereal crops such as wheat, maize or corn, millet, soybean, rice and in roots of potato and cassava, tubers of yam, etc. [17]. Asides the use of starch as food, it is also employed in the textile industry as stiffening agent in fabrics,

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

while the food and cosmetic industry use it as a thickener. In the paint industry it has played the role of filler and thickener [5]. *Ipomoea batatas*, popularly known as sweet potato (Family: Convolvulaceae), is a very important food crop which grows well in the tropics, subtropics and warm temperate regions of the world. Its edible tubers are rich in cellulose and starch amongst other components. Besides cassava, it is the second most popularly consumed tuberous crop in the tropics [1]. Nwachukwu and Ubieko (2020)[27] evaluated the disintegrant properties of starches obtained from cassava, sweet potato and yellow corn compared with corn starch BP as a standard in formulating ibuprofen granules by wet granulation and concluded that the ibuprofen granules formulated with the starches as disintegrants had good flow and compressibility.

Ibuprofen (IBU) is a non-steroidal anti-inflammatory drug and has been very useful in the treatment of arthritis (rheumatoid/osteoarthritis/gout), spondylitis, inflammation, fever *etc*.[6] Chemically, IBU is a propanoic acid derivative (*i.e*. 2-(4-Isobutylphenyl) propanoic acid) with n-octanol/water partition coefficient of 11 [7]. Its profound analgesic effect is mostly related to the inhibition of the enzyme cyclooxygenase-2. However, being a class II type drug (under Biopharmaceutical Classification System), the main problem associated with the oral administration is its extremely low solubility in aqueous media [8,9]. Thus, its dissolution rate is the major limiting step for the successful absorption of the drug to achieve desired onset of action.

This work is targeted at evaluating the disintegrant properties of commercially available corn and potato starches when used as disintegrants in the formulation of ibuprofen tablets.

MATERIALS AND METHODS

The following materials were used as procured: Ibuprofen powder (Himedia laboratories Ltd, Mumbai, India), Starlac powder (Roquette Pharma, North-America), Magnesium stearate (Boai, Nky, China), Talc (Boai, Nky, China), Acacia (J. T. Bayer, USA) Corn starch BP and Potato starch (BDH, England).

Formulation of Ibuprofen Granules

Ibuprofen granules were prepared using the ingredients shown in Table 1. An amount of each of the ingredients that was required for the production of 100 tablets from the granules was calculated, weighed out (except talc and magnesium stearate), added using the doubling up technique, blended to homogeneity and wet granulated. A solution of the acacia was used as the granulating fluid. The granules were formed by wet screening the damp mass of ibuprofen and the other excipients through a 2 mm sieve, dried in the oven (Gallenkamp, England) at 60 ˚C for 1 h, rescreened through a 1 mm sieve, further dried at 60 ˚C in the oven until a constant weight was attained.

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

Table 1: Formula for Ibuprofen Tablet

	BATCH			
Ingredients	I	II	III	IV
Ibuprofen (40 %)	20g	20g	20g	20g
Starlac (qs)	25.25g	24g	25.25g	24g
Maize Starch (5 %, 10 %)	1.25g	2.5g	0.00g	0.00g
Potato starch (5%, 10%)	0.00g	0.00g	1.25g	2.5g
Acacia (5 %)	2.5g	2.5g	2.5g	2.5g
Talc (1 %)	0.5g	0.5g	0.5g	0.5g
Magnesium stearate (1 %)	0.5g	0.5g	0.5g	0.5g
Total (g)	**50**	**50**	**50**	**50**

Key: Batch I: Maize starch 5%, Batch II: Maize starch 10%, Batch III: Potato starch 5%, Batch IV: Potato starch 10%

Characterization of ibuprofen granules

Granules of the different ibuprofen formulations containing the different starches: potato and corn starch BP (represented as batches I, II, III and IV respectively) were evaluated for their bulk and tapped densities, flow rate, angle of repose, Hausner's quotient, sieve analysis and Carrr's Compressibility index.

Bulk and Tapped densities (BD/TD)

A quantity of 20 g of the respective granules of ibuprofen containing potato and corn starches were individually poured into a 200 ml graduated glass measuring cylinder of a Stampfvolumeter (STAV 2003JEF, Germany) with the aid of a glass funnel.

$$BD = \frac{weight\ of\ sample\ in\ gram}{volume\ occupied\ by\ the\ sample} \quad \ldots\ldots (1)$$

$$TD = \frac{weight\ of\ sample\ in\ gram}{tapped\ volume} \quad \ldots\ldots\ldots\ldots (2)$$

The equipment was set to operate at 500 taps and bulk and tapped volumes determined. Determinations for each of the granules was done in replicates and the bulk and tapped densities were calculated using equations 1 and 2.

Flow Rate and Angle of Repose

The flow rate and angle of repose of the ibuprofen granules was determined by using a modification of the Jones and Pilpel method [2]. A quantity of 20 g of the ibuprofen granules was poured into a funnel that was clamped with the orifice of the efflux tube at a height of 3 cm above a flat surfaced platform. The orifice was closed with a metric rule to prevent premature discharge of the granules. On removal of the metric rule, the time it took for the granules to be completely discharged from the funnel was noted. Replicate determinations were done for each of the powders. The flowrate was determined using equation 3.

$$\mathrm{Fr} = \frac{weight\ of\ granules}{time} \quad \ldots\ldots\ldots\ldots (3)$$

The height and diameter of the base of the heap of granule formed on the platform was measured and the angle of repose calculated using equation 4:

$$\mathrm{Tan}\,\theta = \frac{h}{r} \quad \ldots\ldots\ldots\ldots\ldots\ldots (4)$$

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

where θ is the angle of repose, *h* is the height of heap of powder, *r* is the radius of the heap of powder.

Hausner's quotient (HR) and Carr's Index (CI)

The Hausner's quotient was calculated as the ratio of tapped density to bulk density of the powder as shown in equation 5 while the Carr's Index (CI) is determined from equation 6 [3].

$$\text{HR} = \frac{Tapped\ Density}{Bulk\ Density} \quad \ldots\ldots\ldots\ldots\ldots\ldots (5)$$

$$CI = \frac{TD-BD}{TD} \times 100 \quad \ldots\ldots\ldots\ldots\ldots\ldots (6)$$

Sieve Analysis of Granules

This is a procedure used to assess the particle size distribution of a granular material by allowing the material to pass through a series of sieves of progressively smaller mesh size (500µm, 250µm, 150µm, 90µm, 75µm, pan). An accurately weighed 20g of the granules is placed on the top sieve mesh, 500µm, after which the sieve lid is put on and clamped on the Endecott's sieve shaker. This is set to vibrate for 10 minutes and then weighing the amount of material that is stopped by each sieve mesh as a fraction of the whole mass was done.

Compression of Ibuprofen Tablets

The ibuprofen granules containing starches of potato and corn starch BP (Table 1) were compressed into ibuprofen tablets. The talc and magnesium stearate were added immediately prior to compression. A single station Erweka AR400 tablet press (G.M.B.H Heusenstamin Kr Offenbach, Germany) fitted with a set of flat faced punches (12mm diameter) and dies at a compression pressure of 7 Metric tonnes was used to compress 100 tablets per batch at a target tablet weight of 500 mg per tablet.

Characterization of Ibuprofen Tablets

The ibuprofen tablets were characterized 24 h after they were tableted for their physical properties, content of active ingredient and drug release from the tablets using pharmacopoeia methods.

Physical Appearance

The tablets were visually examined to determine their colour, shape and whether defects such as chipping or capping occurred.

Uniformity of Weight of Tablets

The Ibuprofen tablets were checked for variation in tablet weight by randomly selecting and individually weighing 20 tablets from each batch of the formulation

Hardness

10 tablets from each batch of the ibuprofen formulation was collected randomly and the Monsanto hardness tester was used to determine pressure at which each tablet diametrically broke.

Disintegration Time

The disintegration time of the ibuprofen tablets were determined by randomly selecting six tablets from each batch of the formulation and putting each tablet from any given batch into each of the six cylindrical holes of a model ZT-122 disintegration machine (Erweka, Germany).

The disintegration medium was 500 ml of 0.1 N HCl held in a 1 L beaker that was immersed in a water bath. The temperature of both the medium and bath were maintained at 37 ± 0.5 ˚C.

The machine was switched on and disintegration was said to have taken place when the entire tablet had broken down into small fragments and were not retained on the mesh at the bottom of the cylindrical hole. If

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

any mass is retained, it must not be a firm palpable core of the tablet used for the test but could belong to insoluble materials used in the tablet formulation[11 and 19].

Friability

Ten tablets were randomly selected from each batch of the ibuprofen tablet formulations and freed of dust, collectively weighed (*Wi*) and put into one of the drums of the friability tester, model TAR 200 (Erweka, Germany). The machine was operated in a way that the drum rotated at 25 rotations per minute (rpm) for 4 min. The tablets were collected, de-dusted and reweighed (*Wf*) [25] and the percentage friability (F) calculated using equation 7:

$$\text{Fr} = \frac{w_i - w_f}{w_i} \times 100 \quad \ldots\ldots\ldots\ldots\ldots\ldots (7)$$

Thickness

Ten tablets were picked at random from each brand of the Ibuprofen tablets. The thickness and diameter of the tablets were individually determined using a micrometer screw gauge. The mean and standard deviation for each determination was recorded.

Hardness Friability Ratio

The hardness friability ratio is calculated as a ratio between the hardness and friability of each set of ten tablets that were evaluated from each batch of the ibuprofen tablet formulation[15].

Determination of Maximum Wavelength of Absorption of Ibuprofen

A 100 mg/ml stock ibuprofen solution was prepared by dissolving 100 mg of the reference ibuprofen powder in sufficient quantity of phosphate buffer (pH 7.2) in a 100 ml volumetric flask, and making up to the 100 ml volume using the buffer. A portion of the prepared solution was scanned in a UV spectrophotometer model 6405 (Jenway, UK) to obtain the maximum wavelength of absorption at Pure 221 nm.

Dissolution of Ibuprofen

The dissolution of ibuprofen or its release profile from the tablets were carried out using a two station model DT 600 disintegration apparatus (Erweka®, Germany). A tablet from each batch was individually put in 900 ml of phosphate buffer (pH 7.2) solution contained in a 1 L flask kept in a water bath whose temperature was maintained at 37 ± 0.5 ˚C with a paddle speed set at 50 rpm.. Five ml samples were withdrawn from the test media every 10 min and filtered through a filter paper. Five ml of fresh phosphate buffer (pH 7.2) maintained at the bath temperature was used to replace the withdrawn sample after each sampling time. The filtrates were scanned at wavelength of 221 nm and the absorbance readings obtained were converted to concentrations using the standard calibration equation earlier established.

STATISTICAL ANALYSIS

Statistical analysis was carried out with the IBM SPSS version 21 (SPSS Inc., Chicago, Illinois, USA) software using one-way analysis of variance (ANOVA). Results were considered significant at $p < 0.05$.

RESULTS AND DISCUSSION

Some Micromeritic Properties of Ibuprofen Granules

Bulk and Tapped Densities

The results of the bulk and tapped densities of the ibuprofen granule evaluations are shown in Table 2. The tapped densities were all higher than the bulk densities for all the batches of ibuprofen granules which are indicative of volume reduction of the powder

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

bed on agitation. They are thus categorized as compressible granules. There was no significant difference ($p > 0.05$) in the bulk densities. A similar trend was observed in the tapped densities.

Flow Rate

The results of the flow rates of the ibuprofen granules was seen on Table 2. Batch 3 had the best flow. Generally, the granules had good flow attributes and would be good for preparation of ibuprofen tablets with good physical properties such as uniform weight and hardness.

Angle of Repose

The angle of repose of the ibuprofen granules are shown on Table 2 and ranged from 32.00 ± 0.10 - 33.00 ± 0.20˚. There was a significant difference ($p < 0.05$) in the angle of repose of ibuprofen granules for all batches of starches. However, there was no significant difference ($p > 0.05$) between the ibuprofen granules containing 10 % potato starch and 5 % corn starch BP. The granules generally can be classified as having an excellent flow [18,20]. Based on their flowability, they would fill the dies properly during tableting, resulting to tablets with minimal variation in weight.

Hausner's Quotient and Carr's Compressibility Index

The Hausner's quotient of the ibuprofen granules were in the range of 1.16 ± 0.02 - 1.23 ± 0.01 and Carr's compressibility in the range of 14.28 ± 0.33 - 19.23 ± 0.93 % (Table 2). Generally, the granules can be classified as having good flow properties [25]. These flow indices suggest that the ibuprofen granules would be reasonably discharged from the hopper to the die to aid the formation of well filled and compressed tablets.

Sieve Analysis

The particle size analysis results of the ibuprofen granules are shown in Table 2. The mean particle size range was between 333.40µm and 368.15 µm. Larger particle sizes aided the good flow that was observed. Good flowability is desirable in powders/granules to enable proper die filling and production of tablets with minimal variation in weight.

Table 2: Micromeritic Properties

Properties	Batch I	Batch II	Batch III	Batch IV
Angle of repose (°)	33.00 ± 0.20	32.00 ± 0.10	32.20 ± 0.10	33.00 ± 0.20
Tapped density(g/ml)	0.42± 0.00	0.52± 0.04	0.50± 0.02	0.45± 0.03
Bulk density (g/ml)	0.36± 0.01	0.42± 0.02	0.42± 0.01	0.38± 0.20
Carr's index (%)	14.28± 0.33	19.23± 0.93	16.00± 0.42	15.55± 1.02
Hausner's ratio	1.16± 0.02	1.23± 0.01	1.19± 0.05	1.18± 0.02
Mean particle size (µm)	348.95± 0.03	368.15± 0.02	333.40± 0.01	361.65± 0.02
Flow rate (g/s)	2.14± 0.55	2.60± 0.41	3.50± 0.25	2.90± 1.04

Ibuprofen Tablet Parameters Physical properties

The results of some of the physical properties are shown in Table 3. The ibuprofen tablets had no physical defects that could be detected visually.

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

Uniformity of Weight

The result of the assessment of the tablets for uniformity of weight is shown in Table 3. The tablets showed minimal variation in weight and were found to comply with British Pharmacopoeia specifications for uncoated tablets that weigh more than 250 mg. The permissible percentage variation for such tablets is stipulated to be within ± 5 % of the given tablet weight [21,26].

Table 3: Ibuprofen Tablet Parameters

Parameters	Batch I	Batch II	Batch III	Batch IV
Uniformity of weight(g)	0.49± 0.01	0.49± 0.01	0.50± 0.02	0.49± 0.01
Thickness(mm)	3.72± 0.15	3.61± 0.12	3.82± 0.30	3.76± 0.20
Diameter (mm)	12.09±0.01	12.19±0.01	12.08±0.01	11.97±0.01
Crushing strength (kg/F)	5.20± 0.16	6.30± 0.10	4.70± 0.03	5.40± 0.20
Friability (%)	0.88± 0.13	0.85±0.02	0.96±0.10	0.83±0.04
Hardness- Friability Ratio	5.91	7.41	4.90	6.50
Disintegration time (min)	2.41±0.61	2.55±0.73	4.31± 1.10	4.32± 0.97

Hardness

The hardness of the ibuprofen tablets was in the range of 4.70 ± 0.03 - 6.30 ± 0.10kgF (Table 3). All the tablets met with the British Pharmacopoeia recommendation for uncoated tablets which is given as ≥ 4.00 kgF. Such hardness values imply good mechanical strength and physical integrity of the tablets.

Disintegration Time

The disintegration time result reveal that all the ibuprofen tablets disintegrated within 5 min (Table 3) which is quite good for the different batches of tablets and this could be attributed to the wet granulation method of manufacture where starches generally act as super disintegrants[24]. The upper permissible limit by the British Pharmacopoeia is 15 min therefore, the tablets passed the test [22,24].

Thickness

The thickness of the ibuprofen tablets (3.61± 0.12 – 3.82 ± 0.30) are shown in Table 3. There is no significant difference ($p > 0.05$) in the thickness of the different tablets. This suggests that there was fair uniform filling of the granules into the dies as well as uniform compression pressure during the tableting of the granules.

Uncoated tablets are expected to disintegrate within 15 min after oral ingestion to enable release of the active Pharmaceutical ingredient for dissolution and possible absorption in the gastro intestinal tract.

Friability

The ibuprofen tablets were poorly friable as all the batches had friability in the range of 0.83 ± 0.04 – 0.96 ± 0.96%. This is a good attribute as it is an indication of the ability of the tablets to withstand the abrasive stresses that would been countered during packaging, transportation and handling during use. Uncoated tablets are expected to have friability of ≤ 1.00 % [25,2]. The ibuprofen tablets are said to have passed the friability test.

Hardness-friability ratio

The hardness friability ratio is a parameter that is used to assess the mechanical strength of the tablets in relation to the effect of abrasive activities on the tablet. The order of

Archives of Pharmaceutical Sciences and Biotechnology Journal
Volume 2 Issue 2 June 2022 Page 106 - 118 ISSN: 2971_611X
APSBJournal

strength of the ibuprofen tablets were: Batch II >Batch IV> Batch I> Batch III (tablets containing corn starch BP 10 % > potato starch 10 % > corn starch BP 5% >potato starch 5% respectively) (Table 3) signifying that an increase in the disintegrant The drug release profile of the ibuprofen tablets containing starches of potato 5% and corn starch BP 5% is shown in Fig. 1. There was a fast release of ibuprofen from the tablets within 10 min, thereafter the release increased gradually until 30 min. Most of the tablets released more than 80 % of their ibuprofen content within 30 min. Statistically, at 10 min there was no significant difference ($p < 0.05$) in the release of ibuprofen for both batches of tablets. At 30 min, there was still no significant difference ($p < 0.05$) amongst the batches. Comparatively, Batch III of the ibuprofen tablets which contained potato starch BP was the most released within 20 min. It was closely followed by the tablets containing corn starch BP (Batch I). All the batches met with BP requirements which stipulates that up to 80 % of ibuprofen must be released from the tablets within 30 min [23].

concentration led to an increase in the strength of the tablet owing to the binding ability of starches as well as the wet granulation method of manufacture.

Dissolution of Ibuprofen

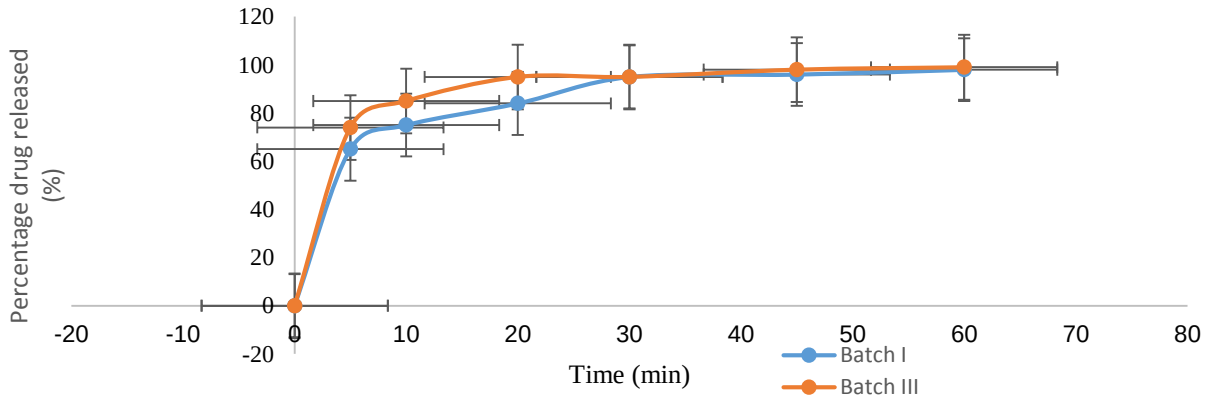

Figure 1: Dissolution profile of ibuprofen tablets containing 5% potato and corn starch BP

CONCLUSION

The starches of potato and corn starch BP had the characteristics of starch namely swelling and hydration in water showing that they would act as disintegrants in tablet formulations. Ibuprofen granules formulated with the starches as disintegrants had good flow and compressibility. The tablets had minimal weight variation, good mechanical strength, friability and disintegration times. The ibuprofen tablet release met the acceptable British Pharmacopoeia set limits. These starches served as good disintegrants in ibuprofen tablets.

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Conflict of interest

The authors hereby declare no conflict of interest.

Authors' Contributions: MBB and AEY were involved in the conceptualization of the paper, MBB, EE, ZYS and AG drafted the manuscript and revised it. All authors approved the final version and accept responsibility for all aspects of the work.

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