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Formulation and Evaluation of Paracetamol Tablets using Solanum Tuberosum Starch as A Disintegrant

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ABSTRACT

Starch is one of the most important pharmaceutical excipients used as a disintegrant, binder, diluent, absorbent, glidant and sweetener. Other applications may include increasing viscosity, defoaming and acting as an emulsifying agent. However, starch used for the above-mentioned functions is corn starch which is imported from abroad which constitutes an economic burden to the government and pharmaceutical industries since a lot of money is used for importation thus affecting the final cost of products formulated from corn starch. The relevance of this research study is to evaluate the disintegration of Solanum tuberosum starch as a disintegrant in the formulation of paracetamol tablets. Irish potatoes are locally grown and thus readily available at the cheapest cost and can be used as an alternative for starch sources such that the cost of production of pharmaceutical products is reduced to meet affordable costs. In this study, Irish potato starch from Solanum tuberosum species was extracted in the pharmaceutics laboratory and then used as a disintegrant to formulate paracetamol tablets by using a wet granulation process. From the results obtained Solanum tuberosum starch passed all the tests according to the BP, 2020 thus making it suitable for use in pharmaceutical processes, the paracetamol tablets formulated using Solanum tuberosum starch had the desired disintegration time especially at concentrations of 10% and 15% thus such.

Keywords: Starch, Pharmaceutical excipients, Disintegrant, Paracetamol tablets, Pharmaceutical products.

INTRODUCTION

One of the most widely used medications in the world to manage pain and fever is paracetamol (acetaminophen). For the treatment of mild to moderate pain, acetaminophen is a popularly prescribed analgesic and antipyretic medication that is also sold over the counter. [1]. Paracetamol (acetaminophen) and ibuprofen are the cornerstones of both over-the-counter and prescription analgesics. The 1950s saw the discovery of paracetamol, while 1962 saw the issuance of the patent for ibuprofen. By the middle of the 1980s, both medications were accessible over the counter and were given for a variety of painful ailments. However, numerous locations around the world. Ibuprofen and paracetamol are efficient analgesic combos. [2]. Other over-the-counter painkillers like Ibuprofen and Naproxen are also used to manage fever and pain. Acetaminophen is frequently used to treat pain and fever in children and adults and is available in pill, liquid, injectable, and rectal forms. In suppository packaging when people consume phenacetin, paracetamol is quickly produced in their digestive tracts. It is the major metabolite (decomposition Product) and it is likely that the antipyretic and analgesic effects of phenacetin were in fact due to paracetamol. There have been some claims that phenacetin's harmful effects were because of the N-oxide, a small metabolite. For the treatment of common headaches, muscular and joint pain, cold and flu symptoms, and fever reduction, paracetamol is utilized. Researchers have discovered a number of hepato-protective medications to treat liver cell damage as a result of drug overdoses, including those involving paracetamol [3]. Tablets are solid pharmaceutical

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dosage forms that include active pharmaceutical ingredients (APIs) with or without appropriate excipients. Pharmaceutical tablets, defined by the Indian Pharmacopoeia as solid, flat or biconvex dishes, unit dose forms created by compressing a medication or medicine combination, with or without diluents [4].

Excipients are substances that are formulated with an active ingredient in medication for the purpose of long-term stabilization, bulking up solid formulations that contain potent active ingredients in small amounts (hence, often referred to as "bulking agents," "fillers," or "diluents"), or to confer a therapeutic enhancement on the active ingredient in the final dosage form, such as improving solubility, facilitating drug absorption, or reducing viscosity [5]. Disintegrates are chemicals that are added to tablet formulations in order to cause tablet fragmentation when submerged in water. When in contact with human fluids, tablets are supposed to break up within a predetermined time frame. This increase in surface area allows for dissolving and, eventually, the therapeutic effects of a medicine. As a result, a disintegrating tablet releases medication at a faster pace than an undamaged tablet. A disintegrate, such as starches, celluloses, algins, gums, etc., helps in the "breaking apart." [6]. The fourth greatest food crop in the world after wheat, rice, and maize is the Irish potato (Solanum tuberosum) [7]. Irish potatoes are a significant food crop farmed in western Uganda and on the slopes of Mount Elgon. Irish potatoes should be cultivated on fertile soils for the best yield because they are high in carbs, most likely starch. However, given Uganda's climatic circumstances, small-scale farmers can cultivate one to four acres, producing 80 to 100 bugs of Irish potatoes [8]. In terms of production on a national scale, it is one of the primary food crops farmed in Uganda in districts like Kabale, Kisoro, Rukungiri, Mbarara, Kasese, Kabarole, Masaka, Mubende, Mbale, Kapchora, and Nebbi. According to the most recent statistics from the Ministry of Agriculture, Uganda produces roughly 450,000 tons of Irish potatoes on 65,000 hectares, with an average yield of about 7 tons per hectare. These Irish potatoes come in a variety of varieties, including Victoria, Kisoro, Kabale, Rutuku, and Nakpot. Studies show that of the Irish potatoes grown in Uganda, 10% are used as seed, 10% are discarded, and 80% are consumed there [9].

The formulation of tablets involves the following processes

Direct Compression: This technique includes pressing the powdered substance directly into tablets. Tablets made using the aforementioned approach are compressed using a machine with one or several stations [4]. *Granulation* is the process of collecting particles together by creating bonds between them. Bonds are formed by compression or by using a Binding agent. The granulation process combines one or more Powders and forms a granule that will allow the Tableting process to be predictable and will produce quality tablets within the required tablet-press speed range. Wet granulation, the process of adding a liquid solution to powders, is one of the most common ways to granulate [10]. Melt granulation, another alternative technique for moisture and heat sensitive APIs is melt granulation. Especially, for formulations consisting of poorly compactible powders. In this process, a molten binder enables the granulation process. Since no liquids are used, the process time and energy requirements are significantly reduced compared to wet granulation. In addition, melt granulation is also beneficial for the manufacturing of high-dose formulations with up to 90 % of API. The dry granulation process is used to form granules without using a liquid solution because the product to be granulated may be sensitive to moisture and heat [10].

Research problem statements

The use of synthetic polymers has been accompanied by a number of drawbacks, including high costs due to imports from other nations, environmental contamination during synthesis, the use of non-renewable resources, side effects, and poor patient compliance [11]. Employees handling methyl methacrylate and poly-methyl methacrylate have reported experiencing skin and eye irritation. The majority of reports of povidone side effects center on the accumulation of subcutaneous granulomas at the injection site and in organs after intramuscular injections. Carbomer-934P has a low oral toxicity at doses up to 8 g/kg, according to investigations on acute oral toxicity in rats. The eyes, mucous membranes, and respiratory system might get irritated by carbomer dust. Therefore, when handling, it is advised to wear gloves, eye protection, and a dust respirator. Studies on rats have demonstrated that subcutaneous injection of a 5% polyvinyl alcohol aqueous solution can result in anemia and infiltrate a number of organs and tissues [11]. Poor biocompatibility, the release of acidic degradation products, poor processing capabilities, and a quick loss of mechanical qualities during degradation are some drawbacks of biodegradable polymers employed in tissue engineering applications. It has been demonstrated that while poly glycolides, polylactides, and their co-polymers have a satisfactory level of biocompatibility, the acidic breakdown products cause systemic or local responses. When poly-(propylene fumarate) was used in rat implant trials, a moderate initial inflammatory reaction was noted [11].

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Aim

To formulate and evaluate paracetamol tablets using *Solanum tuberosum* starch as a disintegrant.

Specific objectives

i. To extract and evaluate properties of Solanum tuberosum starch
ii. To formulate and evaluate properties of paracetamol granules formulated using Solanum tuberosum as a disintegrant.
iii. To evaluate physical properties of paracetamol tablets formulated using Solanum tuberosum starch as a disintegrant.

Research Questions

i. What are the disintegration properties of Solanum tuberosum starch in formulation of paracetamol tablets?
ii. What are the properties of Solanum tuberosum starch properties?
iii. What are the properties of paracetamol granules formulated using Solanum tuberosum starch?
iv. What are the properties of paracetamol tablets formulated using Solanum tuberosum starch?

METHODOLOGY

Materials

Paracetamol, Maize starch, Magnesium stearate, Hydrochloric acid, 0.1N sodium hydroxide, distilled water, Irish potato starch, Sulphuric acid, Paraffin, Nitric acid, Ethanol 96%.

Collection of the samples

The Irish potatoes were obtained from Ishaka market, Bushenyi, Western Uganda. The Irish potatoes variety were authenticated by the botanist in Kampala International University. Raw materials were be obtained from authorized Ramed chemicals-Kampala and well calibrated instruments were used to carry out all investigations.

Apparatus

Tableting machine, disintegration tester, weighing balance, Sieves, friabilator, test tubes, measuring cylinders, mortar, pestle, thermometer, hot air oven, crucible and trays

Study Design

The investigation was carried out using an experimental design, and a thorough evaluation of many parameters was done to examine the properties of Irish potato starch and the qualities of the paracetamol tablets formulated using Irish potato starch. The suitability of Irish potato starch for use as a disintegrant in the production of paracetamol tablets was tested through experiments in comparison to the conventional maize (Zea mays) starch B.P.

Area of Study

The investigation was carried out in the pharmaceutics lab at Kampala International University, Western Campus.

Selection of study setting

Irish potatoes or identified species (Solanum tuberosum L) were randomly selected from vendor, SSalongo in Ishaka central market, Bushenyi district, Western Uganda.

Sample size

46 Irish potatoes of Solanum tuberosum species were collected and produced 160g of starch. Inclusion criteria; the sample only included well sorted Irish potatoes from Solanum tuberosum species. Exclusion criteria; ·the sample didn't include any Irish potato that was diseased or of other Irish potato species apart from Solanum tuberosum species.

Extraction of Solanum tuberosum starch

The [6] method of extraction of Irish potato starch was adopted as shown below; 46 Irish potatoes were thoroughly washed and all foreign materials were removed. The potatoes were peeled and steeped in water for about 24 hours; the steeped potatoes were sliced and then pulverized using Phillips blender. Enough quantity of water was added to the pulp and then passed through a 180µm sieve. The filtrate was allowed to settle and 0.1N sodium hydroxide was added to separate the starch and proteinous materials as well as to neutralize the prevailing slight acidity. Excess sodium hydroxide was removed by washing several times with distilled water until the pH became neutral. The clear supernatant fluid was poured away, sedimented starch was collected on a tray and air-dried on a table at room temperature and later dried in hot air oven at 60^0C [12]. Using pestle and mortar the dried starch lumps was grinded and fine powder passed through 180µm sieve and percentage of yielded starch was calculated as follows; % Starch yielded = ((weight of dried starch/weight of peeled tubers) x100)

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Characterization of extracted Solanum tuberosum starch powder

PH

Using a pH meter, the starches' pH was measured after 2g of starch was added to 3ml of distilled water. The mixture was increased to 20ml by adding boiling distilled water, which was then shaken for a minute before the solution was allowed to cool for roughly 15 minutes. [13].

Moisture Content

Using a hot air oven, the moisture content of the starch samples was measured by precisely weighing and spreading out 1 g of starch powder on the pan. After that, the samples were dried for 90 minutes at 130°C. Calculated and reported as a percentage moisture content, the weight difference caused by moisture loss [13].

Swelling index;

The tapped volume occupied by 10g Irish potato starch powder in 100ml measuring cylinder was recorded V_d. The Irish potato starch was then dispersed in 70ml distilled water and then eventually made up to 100ml. After about 18hours, the standing volume of the sediment starch was recorded V_w. The swelling index was then calculated mathematically and expressed as a percentage as shown below [13].

Swelling index= $((V_w-V_d)/Vd) \times 100$

Particle or True density

The true density of starch was determined by liquid displacement method at 25^0C calculated as weight of starch divided by volume of the liquid it displaces. Liquid paraffin was used as a displacement fluid since starch was practically insoluble in it [13].

Bulk density

A 25 ml measuring cylinder was filled with 10g of starch powder. Carefully flattening the top surface, the volume was measured. Bulk density was calculated using the relation: Mass of starch/Bulk volume [13].

Tapped density

On a cushioned bench, the test tube containing the aforementioned 10 g starch powder was gently tapped 150 times, and the final volume was recorded. Tapped or final bulk density was then be calculated using the relation: Tapped density (g/cm3) = Weight of starch/ Tapped volume [13].

Angle of Repose(θ)

A funnel was clamped with its tip 2cm above a wide piece of paper. The starch powders are then allowed to flow through the funnel until the apex of the cone just touched the tip of the funnel. The mean diameter (D), of the base of the powder cone was determined and the tangent of the angle of repose was calculated using the equation: $\tan\theta = 2h/D$, (Where: h= the height of the heap of powder)

Hausner's ratio

This was calculated as the ratio of tapped density to bulk density of the starch i.e.,

Hausner's Ratio =Tapped density/Bulky density

Carr's compressibility index

Carr's index was calculated from the bulk and tapped density data using the relation:

Carr's index = ((Tapped density- Bulk density)/Tapped density) x I 00

Formulation of paracetamol granules

The wet granulation of massing and screening was used in the formulation of paracetamol granules for all four batches using quantities as formula specifies in the table below [12].

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Table 1: Shows formular for preparation of paracetamol granules.

Ingredients	Batch 1	Batch 2	Batch 3	Batch 4
Paracetamol (%)	69	69	69	69
Corn starch (binder) (%)	10	10	10	10
Corn starch (disintegrant) (%)	–	–	–	15
Irish potato starch (disintegrant) (%)	5	10	15	–
Lactose (diluent) (%)	15	10	5	5
Talc (glidant) (%)	0.5	0.5	0.5	0.5
Magnesium stearate (lubricant) (%)	0.5	0.5	0.5	0.5
Total (%)	100	100	100	100

Ingredients	Batch 1	Batch 2	Batch 3	Batch 4
Paracetamol(mg)	86.25	86.25	86.25	86.25
Corn starch(binder) (mg)	12.5	12.5	12.5	12.5
Corn starch(disintegrant)(mg)	–	–	–	18.75
Irish potato starch (disintegrant)(mg)	6.25	12.5	18.75	–
Lactose(diluent)(mg)	18.75	12.5	6.25	6.25
Talc(glidant)(mg)	0.625	0.625	0.625	0.625
Magnesium stearate(lubricant)(mg)	0.625	0.625	0.625	0.625
Target weight(mg)	125	125	125	125

Four batches of paracetamol tablets were formulated which included three batches of 125mg tablets from Irish potato starch and the fourth batch of 125mg paracetamol tablets formulated from pharmaceutical standard grade maize or corn starch. The paracetamol powder (active pharmaceutical ingredient) and Lactose were carefully weighed using a weighing balance and put into the mortar for trituration using a pestle for about 5minutes. Half of the weighed amount of disintegrant (Irish potato starch) was incorporated intragranulary (before granule formulation) to the powder mix in geometric proportions during trituration process. Adequate amount of the binder solution was added to the dry mixture in the mortar. The wet mass formed was passed through a 710micromillimitres sieve mesh screen and the resultant granules dried at 60^0C for about 30minutes in a hot air oven [12]. The dry granules were then rescreened through the same sieve and further dried for more 30minutes in the hot air oven at the same temperature of 60^0C. The dry granules formulated were then subjected to various analytical tests as shown in the next coverage and thereafter the remining half of the disintegrant i.e. Irish potato starch, glidant and lubricant previously weighed and mixed in a mortar were added in geometric proportions and adequately mixed in readiness for compression by a tableting machine to form paracetamol tablets [12].

Characterization of paracetamol granules

Bulk density

10g of paracetamol granules from each were put into a 100ml measuring cylinder and their volume was recorded followed by calculating bulk density for each batch [12].

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Tapped density

The measuring cylinder having 10g of granules was tapped on a wooden platform 100times followed by recording the volume which was used to calculate tapped density [12].

Carr's Index;

The difference between tapped density and bulk density divided by tapped density was calculated and the ratio was expressed as a percentage [12].

Angle of repose

The hollow tube method was used where a short hollow tube of about 3cm internal diameter was filled with granules when sited on circular horizontal surface of the same diameter. The tube was then withdrawn vertically and excess granules allowed to fall off the edge of circular surface. The height of the heap was then measured using a calibrated ruler [12]. Angle of repose; $\tan\theta = 2h/D$, Where h=height of the heap and D=diameter of the circular base

Compression of granules

Four batches of paracetamol granules were compressed into tablets using a tableting machine in the pharmaceutics laboratory with a fill weight of 125mg followed by adjustment of the Die volume to compress tablets to uniform weight, 72 tablets were formulated per batch. The tablets formulated were then be kept in air tight containers until evaluation tests were conducted to assess their quality [12].

Tablet analysis

Disintegration time test

An Erweka ZT 120 basket and rack assembly was used for the disintegration time test, and the disintegration medium of 0.1 N hydrochloric acid and was kept at a temperature of 37.0± 1.0°C. Six (6) tablets from each batch were used for the test, which was carried out in accordance with the BP 2009's instructions [12].

Tablet friability test

For this investigation, 10 tablets were randomly chosen from each batch of tablets. The pills were cleaned of dust and weighed. The friabilator's drum was then filled with the tablets, and the machine was turned on for 4 minutes at a speed of 25 revolutions per minute before coming to a stop. The pills were then taken out of the friabilator, cleaned, and weighed again [12]. The friability results were calculated from the formula: Friability (%) I 00 = (W 1- W2)/ W1. Where, W1 and W2= the initial and final weights of the tablets respectively.

Hardness test

The hardness tester from Monsanto-Stokes was used for this test. Each batch had five (5) pills drawn at random. Then, after positioning each tablet between the hardness tester's jaws, force was applied while manually manipulating the tester's knob until the integrity of the tablets was compromised. The outcomes are listed in Kgf [14].

Outcome measures or data quality control

The WHO requirement for cGMP equipment was met by the data collecting instruments, all of which were present in Kampala International University's pharmaceutics laboratory.

Data analysis

Using Microsoft Excel, the data was analyzed using qualitative statistics, and the results were displayed in tables and graphs.

Ethical consideration

Ethical approval was sought from Kampala International University research and ethics committee. Permission to use any apparatus to conduct any procedure in the pharmaceutics laboratory was sought and the letter granting permission to use any laboratory equipment was awarded by the research coordinator PROF. KASTURI. The letter was then presented to laboratory technicians in the pharmaceutics before conducting any procedure. All personnel involved in carrying out this research project were wearing protective gears such as lab coats and gloves.

RESULTS

Starch yield

Average weight of peeled Irish potatoes= 3154.12÷46

=68.568g

Percentage of starch yielded = (160÷3154.12) x100

=5.073%

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Characterization of Solanum tuberosum starch

Table 2: Physical properties of starch.

PARAMETER	IRISH POTATO STARCH	BP SPECIFICATION
pH	6.25	4.0-7.0
Moisture content (%)	12	Less than 15%
Swelling index (%)	75	
Particle density (g/ml)	1.33	
Bulk density (g/ml)	0.63	
Tapped density (g/ml)	0.83	
Hausner's ratio	1.33	Greater than 1.26-1.34 (passable flow)
Carr's index%	24.97	5 – 25 (good flow properties)
angle of Repose (θ^o)	32.01	25-40 (good flow)

Characterization of paracetamol granules

Table 3: characterization of paracetamol granules.

PARAMETER	BATCH1	BATCH2	BATCH3	BATCH4	BP specifications
Bulk density (g/ml)	0.385	0.450	0.400	0.417	
Tapped density (g/ml)	0.435	0.526	0.435	0.476	
Carr`s index (%)	11.49	14.45	8.05	12.39	5 – 25 (good flow properties)
Angle of Repose (θ^o)	37.04	35.54	34.59	36.53	25-40 (good flow)

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Table 4: Characterization of paracetamol tablets

PARAMETER	BATCH 1	BATCH 2	BATCH 3	BATCH 4	BP specifications
Friability (%)	0.07	0.23	0.31	0.24	Less than 1
Hardness (kgf)	23.6	14.2	12.4	15.3	4-16
Disintegration (minutes)	20	13	9	10	Less than 15

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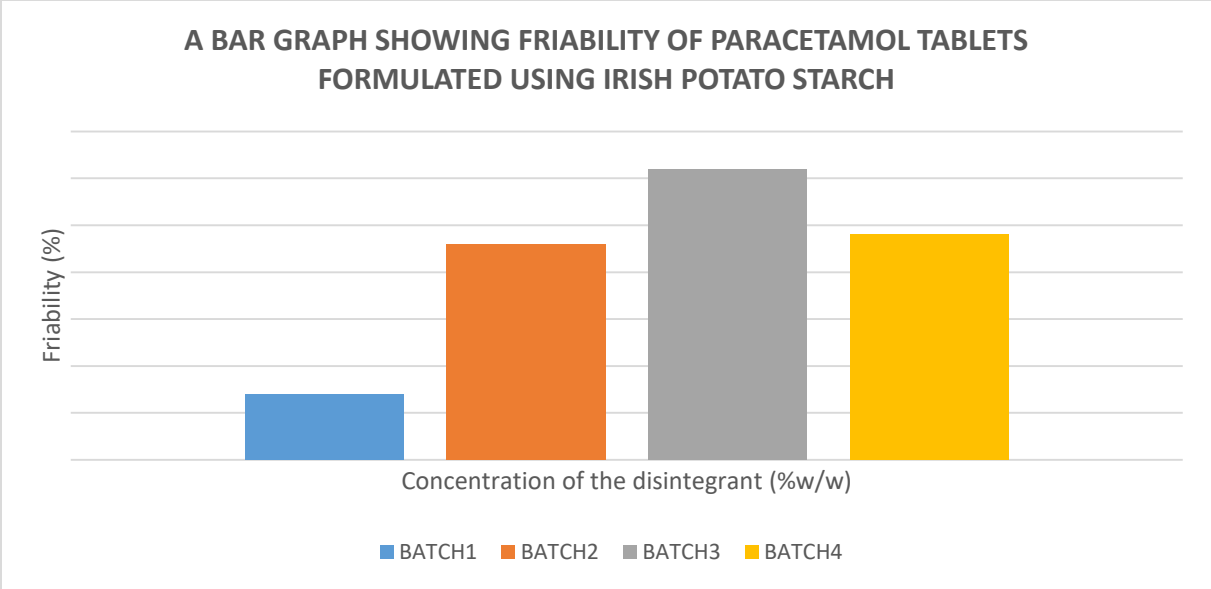

Figure 1: Shows friability of paracetamol tablets.

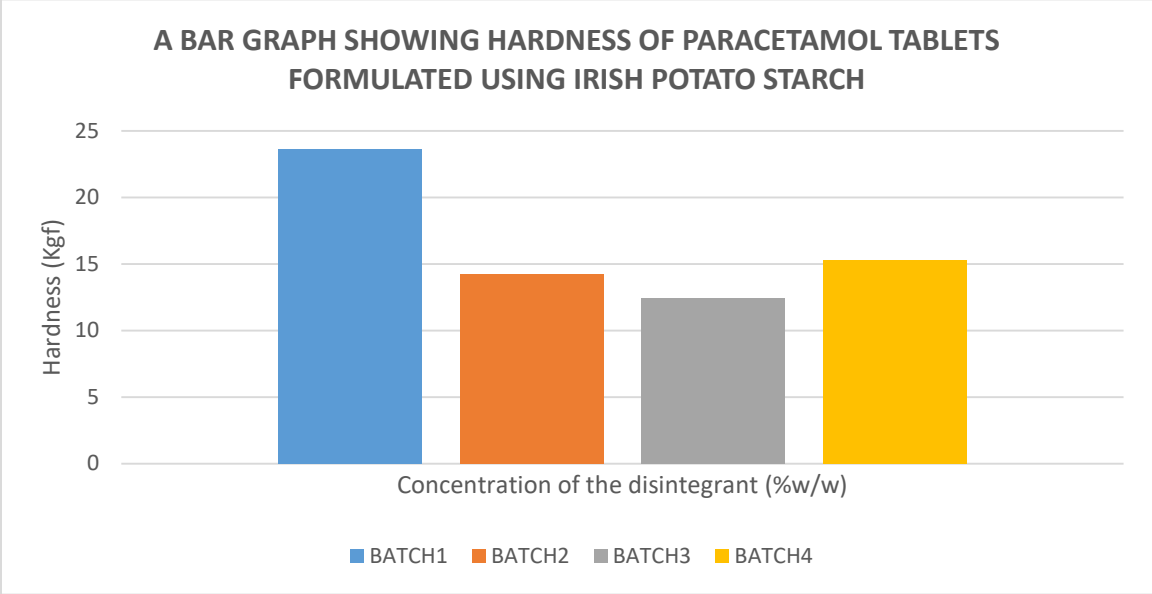

Figure 2: Shows hardness of paracetamol tablets.

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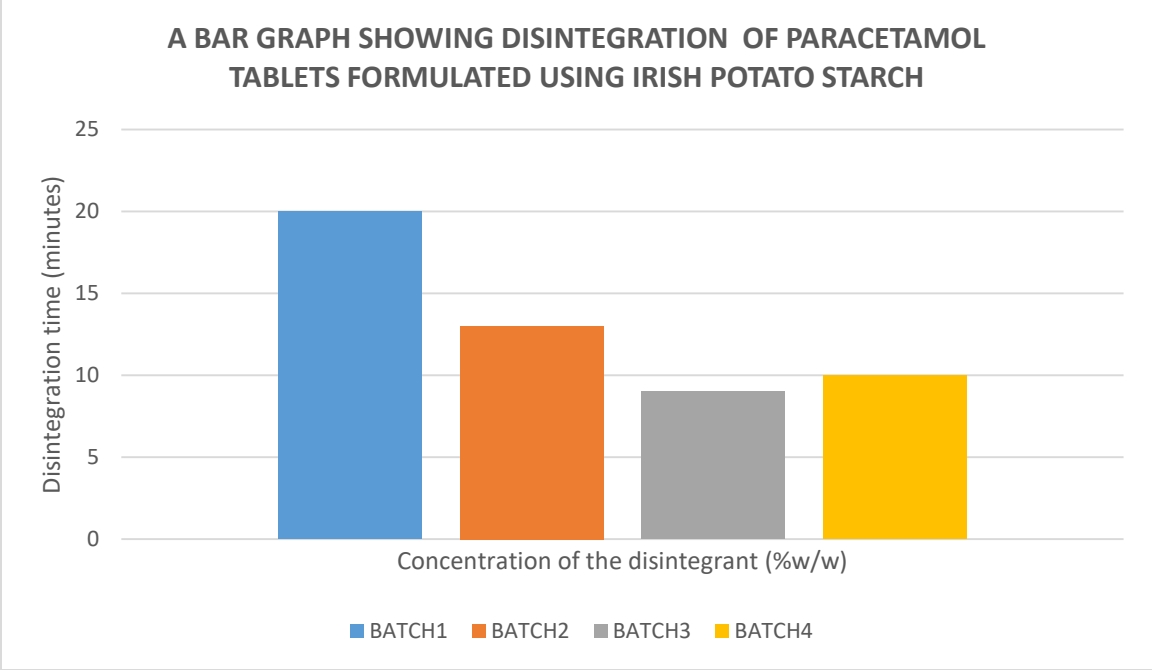

Figure 3: Shows disintegration of paracetamol tablets.

DISCUSSION

Characterization of Solanum tuberosum starch.

Percentage yield of Solanum tuberosum was 5.073% which was far lower than corn starch yield of about 75%. This showed that more Irish potatoes were considerably required to produce sufficient amount of starch to be used in formulation of tablets [13]. PH of Irish starch was 6.25 which was slightly acidic but passable as required by the British pharmacopeia which specifies desired limits within 4.0-7.0 as the recommended thus within acceptable range. Moisture content of Solanum tuberosum was 12% which was within the desired limits of BP,2020 specifications of less than 15% thus indicated that Solanum tuberosum starch had desired moisture content. Particle density of Solanum tuberosum starch was 1.33 g/ml which indicated that its denser and easily the sinks when put in paraffin. Angle of Repose of Solanum tuberosum starch was 32.01^0 which was within required range for pharmaceutical powders of $25\text{-}40^0$ as specified by British pharmacopeia,2020 thus had good flow property for formulation of quality tablets. Bulk density of *Solanum tuberosum* starch was 0.63g/ml and tapped density was 0.83g/ml. This showed that tapped density was more than bulk density, tapping increased compaction of powders i.e., compressed and consolidated powders leading to volume reduction occupied by starch powder since the mass of powder used was constant (RF, 1989). Carr's Index was 24.97% which was within required range 21-25% specified by BP to be passable thus had good flow properties for use in formulation of paracetamol tablets. Hausner's ratio was 1.33 which was passable because was within the required range of 1.26-1.34 as per BP,2020 thus Solanum tuberosum starch can be used for formulation of paracetamol tablets.

Paracetamol granules *Solanum* tuberosum starch.

Bulk density generally increased from batch 1 to batch 3 as the concentration Solanum tuberosum starch as a disintegrant increased from 5%, 10%, 15% respectively. In all the three batches tapped density was slightly higher than bulk density, indicating that tapping lowered volume occupied by granules due to compaction but had no effect on mass of granules because a constant mass of starch was used in the research study (RF, 1989). Carr's index generally decreased from 11.49%, 14.45% to 8.05% i.e., batch1 to batch 3 respectively. Batch 3 granules had excellent flow character granules since 8.05% was below 10% as specified by BP, 2020. Batch l and Batch 2 had good flow character granules since 14.45% and 11.49% were within 11-15% as specified by BP, 2020. This generally indicated that all 3 batches had good flow character as like batch 4 for corn starch with 12.39%, the standard.

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Characterization of paracetamol tablets formulated using Irish potatoes starch.

Disintegration time generally decreased from batch1 to batch3 as the concentration of Solanum tuberosum starch as a disintegrant increased. This is because increased concentration of Solanum tuberosum starch as disintegrant from 5%, 10%, and 15% increased the quantity of disintegrant which increasingly enhanced break down of paracetamol tablets when placed in disintegration apparatus. In batch1, tablets took long disintegration time of 20 minutes because the concentration of a disintegrant was low above 5% thus couldn't enhance disintegration of tablets more rapidly. This is because at low concentration the Solanum tuberosum starch was acting as a binder [15]. Batch 2, batch 3 and batch 4 showed disintegration time of 13minutes, 9 minutes and 10 minutes respectively which were within required range as specified by BP of not more than 15 minutes to be passable. This is because increasing concentration of Solanum tuberosum starch increases its disintegration activity and inhibits binding tendency, indicating that concentrations of Solanum tuberosum starch at 10% and 15% worked effectively in the formulation of paracetamol tablets as per BP,2020. Friability for all the 4 batches i.e. 0.07%, 0.23%, 0.31%, 0.24% respectively was within required standards as per BP of less than 1% for tablets formulated using wet granulation process. However, friability increased from batch1 to batch3 as the concentration of the disintegrant increased for example batch1 had a lower concentration of disintegrant of 5% compared to batch 2 and batch 3 with 10% and 15% respectively [16-19]. This made tablets liable to attrition as the concentration increased making it easy to be broken down and friability increased as well (RF, 1989). Hardness of tablets. Generally, decreased as concentration of disintegrant increase i.e., batch1 to batch3 (23.6kgf, 14.2kgf, 12.4kgf) respectively. Batch2 and batch3 values were within desired range of 4-16kgf as specified by Bp. As the concentration of disintegrant increased from 5%-15%, amount of disintegrant increased in tablets, decreasing the strength of tablets to resist force generated by hardness tester machine. The increased disintegrant concentration increased breakdown of tablets and lowered concentration inhibits breakdown because starch acted as a binder, causing increase in tablet strength. Batch 4 had cornstarch at 15% concentration as a disintegrant which indicated a high amount of disintegrant, decreased strength of tablets than for batch1 whose disintegrant concentration of 5% increased strength for a tablet to be breakdown.

CONCLUSION

Solanum tuberosum starch can be used as a disintegrant at concentrations of 10% and above but should not below 5%w/v. This is because concentrations of 5% of the Solanum tuberosum as a disintegrant took of more time than recommended by BP,2020 of less than 15minutes for tablets to disintegrate thus may not be of therapeutic advantage. This is because absorption of paracetamol tablets only occurs after the tablet disintegration. Solanum tuberosum starch had good disintegration activity at concentration of 10% and 15%. This starch had good comparable characteristics that it can be used as an alternative for cornstarch in formulation of paracetamol tablets, currently used by most of pharmaceutical industries because its cheap and readily available.

RECOMMENDATIONS

Further studies should be conducted on; Drug compatibility studies, toxic metal content of Solanum tuberosum starch, dissolution studies of paracetamol tables formulated using Solanum tuberosum starch, disintegration activity of Solanum tuberosum starch concentration of 20%w/w and above which can be applied in formulation of immediate release paracetamol tablets.

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