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Starch: Natural sources and its pharmaceutical applications

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ABSTRACT: For millennia, tropical roots and tubers, grains, cereals, and fruits have been staple foods for millions of people living in hot and humid climates around the world. Some of these crops thrive with little or no artificial assistance. Because starch is a key component of many tropical crops, they are good sources of starch that could be employed as medicinal excipients. Some of these starches have recently been studied for application in pharmaceutical tablet formulations as fillers, glidants, binders, and disintegrants.

Starch can be obtained from various of plants sources. The physicochemical composition of starch is affected by the source of starch, the ambient circumstances during starch maturity, and the age of the plant. This is because of the effect they have on critical factors especially the amylose amylopectin content of the starch as well as their relative quantities. The size and distribution of starch granules, as well as the quantity of minor components like phosphates and lipids, as well as the nature of interactions with amylose and amylopectin, are all influenced by these variables. This review covers current knowledge about tropical plant starches that have been examined as pharmaceutical excipients and their potential utility.

KEYWORDS: Native Starch, Amylose, Amylopectin, Genus, Excipient.

I. INTRODUCTION

Starch is one of the most abundant natural carbohydrates stored in plants.The physicochemical features of unmodified starch affect its functionality in its vast use as a pharmacological excipient, especially as a binder and disintegrant.Tropical roots and tubers, grains, cereals, and fruits have long been staple foods for millions of people around the world. They have a high starch content (40–80 percent w/w db), making them viable industrial starch suppliers. Some of these plants survive with little or no artificial help.

The use of starch as an excipient in new drug delivery systems for nasal, oral, periodontal, and other site-specific delivery systems has been studied. Starch is also utilised in topical medicines; for example, it is commonly employed in dusting powders due to its absorbency, and it is used as a protective coating in skin ointment formulations. Starch mucilage has also been used as an emollient, as the foundation of some enemas, and to treat iodine toxicity.Starches are widely available and have proven to be particularly effective in tablet production due to their inertness, low cost, and use as fillers, binders, disintegrants, and glidants.

Pure starch is a white, amorphous, generally tasteless powder that is odourless and insoluble in water and other common organic solvents in its natural state. It is the energy storage form of plant materials and is one of the most extensively distributed chemical molecules in nature. Starch is made up of colourless, highly refractive particles whose size and form are determined by a variety of factors, the most important of which is the starch's source. The crystalline component of a starch granule is made up of alternating sections of amorphous and crystal-line lamellae viewed as rings. Starch is a carbohydrate that is chemically made up of two identical carbohydrate molecules: amylose and amylopectin. Amylose is a linear polymer with 1,4-glycosidic linkages, whereas amylopectin is a branched polymer with 1,4-glycosidic bonds. Because of their inertness and low cost as a pharmaceutical excipient, starches are widely available and have proven to be particularly effective in tablet manufacture.

II. THEORY

Natural Sources of Starch:

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1. Roots and tubers:

Plants that produce starchy roots, rhizomes, corns, stems, and tubers are known as root and tuber crops. They include 70–80 percent water, 16–24 percent starch, and trace amounts of proteins and lipids (4 percent).[1] Some of the root and tubers grown for edible purposes in the tropics that have been studied and evaluated as excipients are: yams (Dioscorea species including D. alata, D. dumetorum, D. oppositifolia, D. rotundata, D. esulenta, D. cayenensis), sweet potato (Ipomoea batatas).

1.1. Yams:

Yams are a staple root crop grown in many countries of Africa and Southeast Asia. They are members of the Dioscorea genus, which contains over 600 species. Dioscorea dumetorum; D. oppositifolia Thumb; D. alata DIAL2 and D. rotundata Poir, D. bulbifera, D. esculenta Lour, and D. cayenensis Lamk are the most cultivated and economically important species in West and Central Africa that have been evaluated as excipients in the food and pharmaceutical industries. Yam tubers are high in starch (70–80 percent dry weight basis) and are commonly consumed in chunks, flour, fufu, and slices obtained through boiling, drying, fermenting, frying, milling, pounding, roasting, and steaming.[2]

The natural forms of yam starches were used as binding agents and disintegrants in tablet formulations, and they were compared to corn starch. The authors concluded that the starches from the four species of yam compared promisingly and, in some cases, showed better efficiency as binder and disintegrant than corn starch and could be further developed for use in commercial tablet formulation.[3]

1.2. Sweet potato (Ipomoea batatas):

Sweet potato (Ipomoea batatas L. Lam) is one of the world's most adaptable and nutritionally valuable food crops. The plant is water-stress tolerant, has a short growing season, and can adapt to a wide range of environmental circumstances.[4] Sweet potato has the ability to be used as a tablet raw material. However, it needs chemical modifications to produce derivatives with excellent pharmaceutical characteristics. The primary goal of this study was to use sweet potato starch (Ipomoea batatas Lamk) as a chemically modified tablet excipient.[5]

Sweet potato roots contain 80-90 percent carbohydrate, mostly in the form of starch, making them a valuable raw material for the starch industry. In China, Vietnam, Korea, Taiwan, and the Philippines, sweet potato is a major source of starch. The main carbohydrate in roots is starch, which accounts for 73.7 percent to 84.9 percent of the dry weight of the root. Sweet potato previously had a total starch level of 61.5 percent dwb on average.[6]

Isolation of sweet potato starch (SPS) from sweet potato is given below;

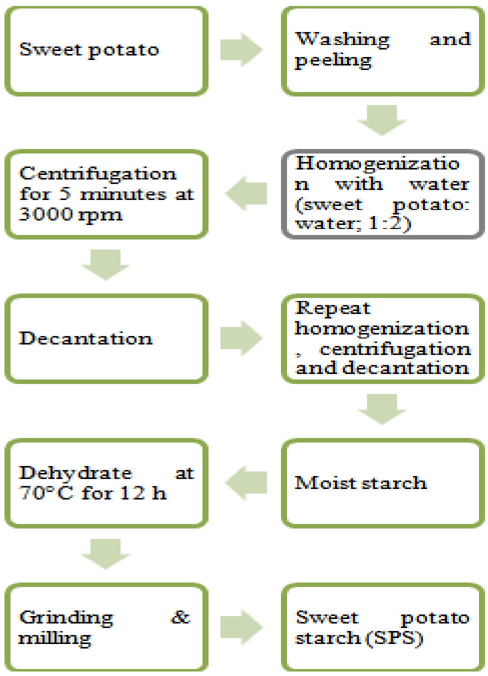

Figure 1: Isolation of SPS from sweet potato[6]

2. Grains and cereals:

2.1. Sorghum:

Sorghum, in the Gramineae family, is a genus of grasses that includes one species that is grown for grain and many others that are used as fodder plants, either cultivated or in pasture. Plants are grown in warmer climes all over the world, and certain species are native to tropical and subtropical locations across the globe. Sorghum bicolor L. Moench, a major food crop in Africa, Central America, and South Asia, is one of the species. The majority of types are drought and heat resistant, as well as inexpensive. Food (as grain and in sorghum syrup or "sorghum molasses"), fodder, alcoholic beverage manufacture, and biofuels are all products of sorghum.[7]

Due to its drought endurance and low input costs, sorghum is a popular cereal grain. Sorghum is the fifth most important cereal grain in the world, both in terms of quantity and importance. Grain sorghum is mostly composed of starch, which accounts for approximately 70% of the dry grain weight. The ratio of amylose and amylopectin, the two primary polymers in the starch granule, as well as the structure of amylopectin, influence several essential physicochemical, thermal, and rheological aspects of starch. Starch gelatinization and retrogradation, paste viscosity, gelation, and R-amylase digestibility are all influenced by amylose concentration. Starch gelatinization and retrogradation capabilities were shown to be influenced by the fine structure of amylopectin (chain-length distribution).[8]

Due to its favourable physicochemical qualities and relative inertness, starch is a multipurpose excipient in tablet formulation and can be employed as a binder, disintegrant, or filler. In recent years, pharmaceutical researchers have focused more on the extraction, development, and application of starches in dosage for formulation. Native starches have also been pregelatinized to produce cold water-swellable starches with better flowability. Thermal methods can be used to pregelatinize starches, which should alter a variety of properties, including compressibility.[9]

2.2. Pigeon pea:

Pigeon pea, also known as tropical green pea, is a tropical cereal plant (Cajanus cajan L. Millisp., family Fabaceae) commonly farmed in over 25 tropical and subtropical nations in Asia, Africa, and Central America. Pigeon peas are a forage/cover crop as well as a food source (dry peas, flour, or green vegetable peas). Pigeon pea is consumed after boiling in several of these countries.[10]Starch from pigeon pea (Cajanus cajan L) was isolated and some of the important characteristics determined. The yield of starch was 29 .7% on a whole seed basis. The shape of the starch granule was oval to elliptical to irregular, with granules 8-32 µm in diameter. Scanning electron micrographs revealed the presence of smooth surfaces with a large number of grooves.[11]

Table 1: Chemical composition percent(%) and some of the properties of pigeon pea starch[11]

Characteristics	Composition percentage
Yield (percent initial material)	29.70
Moisture	10.90
Ash	0.03
Nitrogen	0.02
Starch damage	2.00
Lipid	
Acid hydrolysed	0.13
Solvent extracted	
Chloroform-Methanol	0.03
1-propanol-water	0.10
Amylose content (percent of total starch)	
Apparent	28.50
Total	29.30
Amylose complexed by native lipid	2.70
Starch granule characteristics	
Granule shape	Ovel to elliptical to irregular
Granule size (µm) micrometre	8-32

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3. Fruits:

3.1. Plantain starch:

Plantain (Musa paradisiaca Normalis, Musaceae) is a staple crop for over 70 million people in Sub-Saharan Africa. It is often cultivated for its carbohydrate content, and it can be eaten as an unripe or mature fruit. Boiling, roasting, or frying are all traditional techniques of processing. It can be used as a component of baby food once it has been processed into flour.[12] Chemical, physical, physicochemical, rheological, and morphometric properties of starch extracted from unripe plantain (Musa paradisiaca normalis) were investigated. The average starch yield was 10-12 percent, the granules were unevenly formed, and the size ranged from 10 to 50 particles. The starch's average chemical makeup (percentage of dry matter) was as follows: 0.09 g of crude fat, 0.26 g of crude fibre, 0.02 g of ash, and 0.03 g of total sugar (as non-reducing sugar).[13]

Table 2: Composition (% of dry basis, except moisture) of Native Plantain starches.[13]Note: ND- Not detected.

Component	Plantain content
Moisture	9.87
Total starch	99.60
Crude protein	ND
Crude fat	0.09
Crude fiber	0.26
Ash	0.02
Total sugars	0.03
Reducing sugars	ND
Non red. Sugars	0.03
Phosphorus	ND

In tablet formulations, plantain starch has been found to have binding and disintegrant characteristics. The tensile strength and disintegration time of tablets increased as the concentration of starches was raised when utilised as a binding agent in tablet formulation. Plantain starch-based tablets showed a stronger tensile strength but a faster disintegration time than maize starch-based tablets. The authors concluded that plantain starch would be more useful where faster disintegration of tablet is desired.[14]
Additionally, pregelatinized plantain starch has been demonstrated to be more effective as a binding agent in conditions requiring strong bond strength with low lamination and capping issues.[15]

3.2. Breadfruit:

The seedless breadfruit, (Artocarpus cummunis Forst) belongs to the Moraceaefamily and is native to Malaysia. It has now spread throughout the South Pacific and Caribbean, and was brought to South Western Nigeria via the Caribbean. Typically, the fruits are gathered and consumed as a source of carbohydrate. It's similar to yam in that it may be boiled, crushed, or ground into flour, and it's been called a poor man's yam replacement.[16]

The core of the breadfruit had the highest moisture, ash, protein, fat, and crude fibre content, whereas the pulp had the highest carbohydrate, starch, nitrogen free extract, and organic matter content. The core had the most total free and reducing sugars, whereas the peel had the least. The reducing sugars sucrose, glucose, and fructose followed a similar pattern, but the flatus-producing oligosaccharides raffinose (0.1%) and stachyose (0.05%) were present in the core. Only rafinose (0.05%) was found in both the peel and the pulp. On a dry weight basis, extracted starch from breadfruit pulp accounted for 58 percent of total starch content, with minimum quantities of ash, lipid, and protein and 98.6% starch.[16]

Table 3: Proximate composition of breadfruit starch[17]

Parameters	Values (%) Values (%) Values (%)
Crude protein	0.53±0.01
Moisture content	10.83±0.01
Ash content	1.77±0.01

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Fat content Amylose content Amylopectin content	1.77±0.01 1.77±0.01 0.39±0.01 22.52±0.00 77.48±0.00

Tablet binders, lubricants, glidants, and disintegrants are all possible uses for breadfruit starch. With an increase in breadfruit starch concentration, the disintegration time was increased as well as the hardness was increased. As a result, it was discovered that breadfruit starch can be used as a tablet binder.[18]

Starch as pharmaceutical excipient:

Starch is a polymer found in many green plants. Because of its nontoxic and non-irritant qualities, as well as its low cost, simplicity of modification, and variety of usage, starch has risen to the top of the list of polymers used as medicinal excipients. Starch is employed as a diluent, disintegrant, binder, and lubricant in many traditional tablets and capsules. Starch has important intrinsic qualities that have allowed it to be used in pharmaceuticals. It's also been employed for a variety of specialised drug delivery applications, such as the administration of difficult molecules and the targeting of specific body areas.[19]

Native starch is starch that has been separated from its botanical source with little processing, allowing the intrinsic physicochemical qualities to be preserved following processing. Starch may be stored for an extended period of time if it is kept dry. The use of starch as a pharmaceutical excipient in various drug delivery systems and formulations is appealing owing to its physicochemical and functional qualities. As pharmaceutical excipients, both natural and modified starches are employed. Native starch is appealing for usage as a pharmaceutical excipient due to its white, soft, silky dryness, as well as gelling and viscosity imparting qualities. Furthermore, when they are adjusted, new properties are influenced, which expands their functions and applications, making them more efficient in both traditional and unique drug administration.[20]

Starch as a Binder:

Binders are used to hold the active pharmaceutical ingredient and inactive substances together in a cohesive mix in the creation of solid oral dosage forms. Binder products are usually classified according to the manufacturing procedure that will be employed. Dry binders used for direct compaction must have cohesive and adhesive forces such that particles agglomerate when compacted. Binders used for wet granulation are hydrophilic and soluble in water and are usually dissolved in water to form a wet mass that is then granulated. Binders function as binder for both direct compression and wet granulation.[21]

Starch compresses effectively as a dry binder, mostly deforming plastically. Due to its granular shape and superior adhesive properties, it has been found to generate cohesive dry mixes. Starch works very well in tablet manufacturing via wet granulation applications because of its partial cold-water solubility, and it serves as both a disintegrant and a binder. Starch and Star Cap Co-Processed Starch Excipients are good binders in capsule filling procedures, enhancing the regularity of the capsule fill and generating a stable capsule plug.[22]

Because different qualities are required for each function, starch as a binder should not be mistaken with starch as a disintegrant or diluent. Compressibility is the most significant feature in a binder. Under direct compression, granular starches and traditional pregelatinized (i.e., cooked, nongranular, cold-water-dispersible starches) do not bind well. Physically modified, partially cold-water-swelling, cold-water soluble compacted starches are said to be effective as binders and disintegrants in direct compression tabletting. The modification, which involves passing starch through closely spaced steel rollers with or without supplemental thermal energy, disrupts and fractures at least some of the granules, resulting in a mixture of birefringent and nonbirefringent granules and fragments, as well as completely solubilized starch (typically about 10-20 percent). The compressed material is crushed into particle size fractions and then categorised. Although the resultant starch has some direct compression binding, its loading potential is minimal, and it is frequently necessary to utilise an auxiliary binder.[23]

Starch as Disintegrant:

Native starches originating from botanical sources are extensively used as disintegrants in

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pharmaceutical tablet formulations, usually in the 2–10% w/w range. In tablet formulations, starch and other disintegrants can be added intragranular (endodisintegrants), extragranularly (exodisintegrants), or a combination of the two (endo-exo-disintegrants). Starch is added to the powder mixture and granulated in intragranular addition, whereas dry starch powder is added to the produced granules in extragranular addition. Half of the starch is added intragranularly, and the other half is added extragranularly, in intragranular addition. A disintegrant's disintegrant effectiveness is influenced by the way it is incorporated. When added extragranularly rather than intragranularly, starch has a faster disintegrant effect.[25]

When exposed to water, it is widely assumed that it functions as a disintegrating agent by a swelling effect. When exposed to a 95 percent relative humidity atmosphere at 27 degrees, starch will absorb around 20% of its weight in water in 24 hours. They make no mention of any volume changes that occur as a result of the process. It claims that starch is insoluble in cold water in its native state, but absorbs 25 to 30 percent and does not swell significantly. the disintegrating effect is due to capillary action rather than swelling.[26]

Before the active medication material is fully released from the tablet, disintegration causes it to break up into component granules, exposing a larger surface area of the tablet to the dissolution media. The disintegrant has probably become the most significant excipient in a tablet to allow immediate drug release because an instant release tablet formulation of a medicine is usually not helpful until its active component is made available for absorption. Although most research is focused on modified release dosage forms because of their benefits such as reduced dosing frequency and improved patient adherence, reduced side effects, and increased duration of therapeutic action, immediate release dosage forms continue to play an important role in drug delivery, particularly in disease conditions that require rapid onset of action.[27]

Musiliu et al (2009), conducted research "Disintegrant activities of natural and pregelatinized trifoliate yams, rice and corn starches in paracetamol tablet" Results is shown by[28] Fig.3:

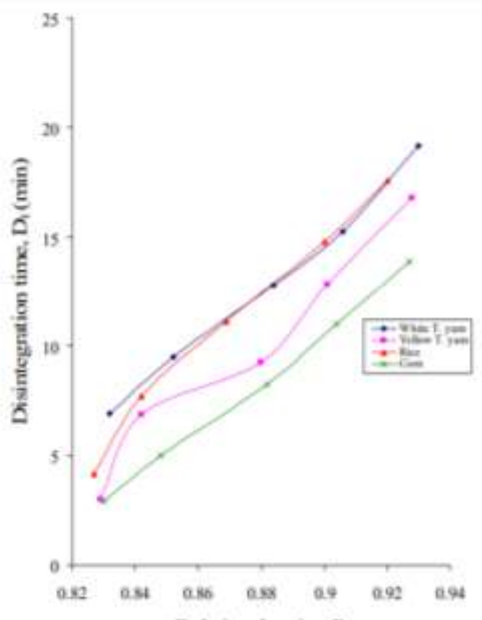

Figure 3: Plots of disintegration time (Dt) versus relative density (R) for paracetamol tablets formulated with 6% w/w natural starch exo-disintegrants (Musiliu et al., 2009)[28]

Starch as Diluent:

A class of natural diluents includes native starches. They've been utilised to make standardised colourant and medication triturates, as well as to make mixing and handling easier. Native starches are an insoluble diluent with a number of desirable intrinsic qualities, including no hazardous interactions with most common APIs and excipients, no physiological or pharmacological activity, and consistent physicochemical and functional properties.[19,29]

To provide satisfactory performance in a tablet dosage form, a diluent should be:

- Inert so as not to cause pharmacological activity of its own.
- Compatible with the drug substance and other excipients used in the formulation.
- Non-hygroscopic so the formulation does not absorb significant amounts of moisture from its surroundings.
- Compactable and of similar particle size to the active ingredient.[21]

Tablets should not be less than 50 mg in weight and 3 mm in diameter in order to achieve appropriate handling and weight uniformity during manufacture. Diluents are added and constitute an intrinsic component of the recipe to accomplish and enable appropriate handling and mixing of highly potent, low dose APIs. Diluents, often known as fillers, are excipients used to increase weight, facilitate mixing, and improve content uniformity in low-dose traditional formulations such as tablets, capsules, and granules.[29]

Though native starch is inexpensive, its usage as a diluent will be determined by criteria such as relative concentration, formulation technique, and the qualities of the APIs and other excipients to be utilised.[30]

Modified Starch Used as a diluent, binder &disintegrating agent**:**

Sta-Rx 1500and Celutab free flowing Directly compressibleUsed in chewable tablet in place of manitol because of their sweetness and smooth feeling in mouthContain 8 to 10% moisture & may increase hardness after.[31]

Starch as Glidant:

Glidants are additive compounds that improve the flowability of a powder by lowering interparticle friction, surface charge, and cohesiveness, resulting in a lower angle of repose. They are frequently introduced as a dry powder immediately prior to direct compression. Due to their inability to reduce die wall friction, glidants are typically used in conjunction with lubricants. The amount of glidant employed is crucial, since too much can impair the flow qualities of the powder combination by restricting its flowability.[32]

Starch is one of the glidants that can be employed in the production of traditional tablets and capsules, and it is added at a concentration of 2–10% w/w.[33]

It is often a hydrophilic glidant. Other starches such as cassava, yam, and fonio have also been explored as potential glidants in tablet manufacture. The glidant characteristics of native starch in pharmaceutical granules and powders can be evaluated using measures such as flow rate, flow factor, and angle of repose. The particle size is an important parameter that determines the glidant efficiency of prospective materials: The smaller the particle size, the more efficient the glidant qualities.[19,33]

Starch as Lubricant:

Lubrication is required for pharmaceutical activities such as blending, roller compaction, tablet production, and capsule filling to minimise friction between the surface of manufacturing equipment and organic materials and to enable the operation's continuation[34]. Pharmaceutical lubricants are substances that are added to tablet and capsule formulations in very small amounts (typically 0.25 percent to 5.0 percent, w/w) to improve powder processing qualities. Lubricants play a significant role in manufacturing because they reduce friction at the interface between a tablet's surface and the die wall during ejection, reducing wear on punches and dies; they also prevent tablets from clinging to punch faces, capsules from sticking to dosators, and tamping pins.[35]

During the manufacturing of tablets and capsules, starches are utilised as an antiadherent and lubricant at a concentration of 3–10% w/w. Starch's antiadhesive characteristics prevent crushed powders/granules from clinging to punch faces and die walls, or, in the case of encapsulation, from sticking to dosators and tamping pins of encapsulates. During the compression and ejection processes, starch acts as an intermediary layer between the tablet constituents and the die wall, reducing friction.[36]

Starch in artificial red cells:

Potato starch, in example, has been utilised to create artificial red blood cells that have a high oxygen-carrying capacity. By self-assembly, haemoglobin (Hb) was encapsulated with long-chain fatty acid grafted potato starch.[37]

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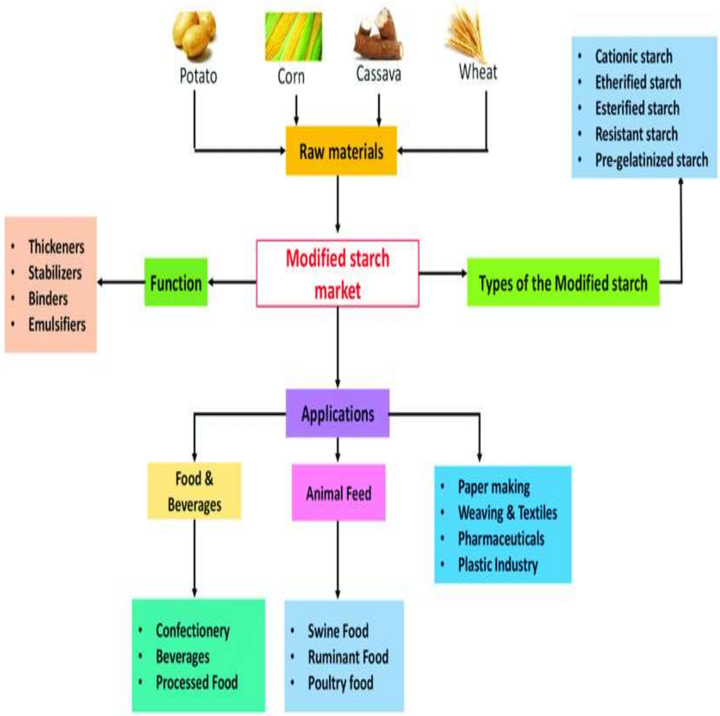

Figure 4: Modified starch market share by the application (Reproduced from: Modified starch market size, by product 2014–2025 (USD billion) Grand View Research, Inc.[38]

III. CONCLUSION

Tropical starches have great commercial value as pharmaceutical excipients. The majority of these starches have been physically or chemically changed in order to improve their qualities and make them more suitable for pharmaceutical drug formulations. However, there is a need to fully characterise these starches and create pharmaceutical grade excipients that could be employed in drug formulation. This will bring value to some of these underutilised crops while also supplying starch with unique properties for specialised applications. Starch is a naturally occurring substance that is commonly available. Because of its various physical and functional qualities, it is adaptable and has found application in a wide range of sectors. Because of the high amount of hydroxyl groups on the surface, a variety of modifications or derivatives can be created. It is widely used as an excipient in the pharmaceutical industry, particularly as a disintegrant, binder, diluent, glidant, and lubricant in the formulation of solid dosage forms.

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