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A Review on Starch Based Natural Binders as Excipient in Pharmaceutical Formulations

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ABSTRACT

Now a day in the developing pharmaceutical industry, natural excipients play a vital role in ensuring the standards of pharmaceutical dosage forms. Natural excipients have several advantages that make it superior to the synthetic one. Starch is a very high quality natural excipient. Starch is abundant and most common naturally occurring one. Apart from being as a binder, starch has many other uses in the formulation of solid dosage form.

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INTRODUCTION

Always tablet dosage form remains most commonly prescribed one and most demanding one due to ease of administration. It is stable compared to other dosage form [1, 2]. Excipient performs as a fundamental component in formulation process to convert the drug into the tablet formulation. This ensures suitable dosage form with adequate quality and delivers the drug into intended site after administration [3].

Natural polymers are always safe than the synthetic one like PVP. Many of these excipients are drawn mainly from natural sources of plant, animal, mineral origin and undergo a high degree of the purification process to confirm their safe, nontoxic character [3,4].

Binders are always used in the formulation of solid oral dosage forms to hold the drug and excipient together in a cohesive mix. Binders are usually varied based on the manufacturing process to be used. Binders are excipient which ensures proper flow characteristics and provide sufficient cohesiveness to the granule there by the tablet retain their quality after compression during the shelf life.so selection process with due attention is essential for matching all formulation and process needs[5,6,7]. The binders can be added either in dry form or in solution to the tablet preparation by wet granulation, which convert the powder into granules with good flow property and cohesiveness. Flow property is essential to produce tablet with required weight and sufficient strength. The solution binders dissolved in a solvent (eg: water/alcohol), the dry binders are added to the powder blend [8,9]. Different binding agents show different mechanical strength and drug release characteristics. So, the binding agents should be carefully selected by considering parameters like viscosity, wetting capacity, dissolution kinetics. The quantity of binder required in given system selected by optimization studies using suitable parameters.

The starch was one of the earliest excipients in tablet formulation. Starch has multifunctional characteristics. The starch isolated from different source used for different functional properties in tablet manufacturing [10]. Starch is a complex carbohydrate and starch granules usually contain two major carbohydrate amylopectin and amylose. Starch commonly used as binder, disintegrants, diluent, and glident in tablet formulation. It can undergo a wide range of physical and chemical modification, which yields improved functionality [8,10].

IDEAL PROPERTIES

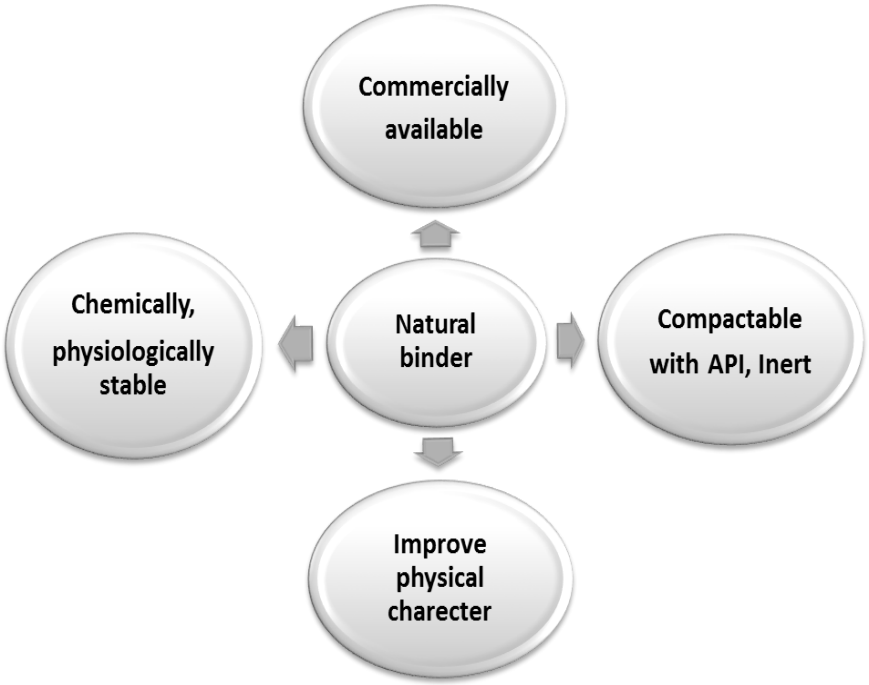

Figure No:-1; Characters of natural binders used as excipient [7].

ADVANTAGES OF NATURAL BINDERS [5, 7]

- Wide variety of natural binders.
- Low toxicity & low cost.
- Biodegradable& easily available.
- Most of them produced from edible source.
- Improve organoleptic properties of drug.
- Improve drug release characteristics.
- No side effects.

MICROSCOPIC VIEW OF STARCH

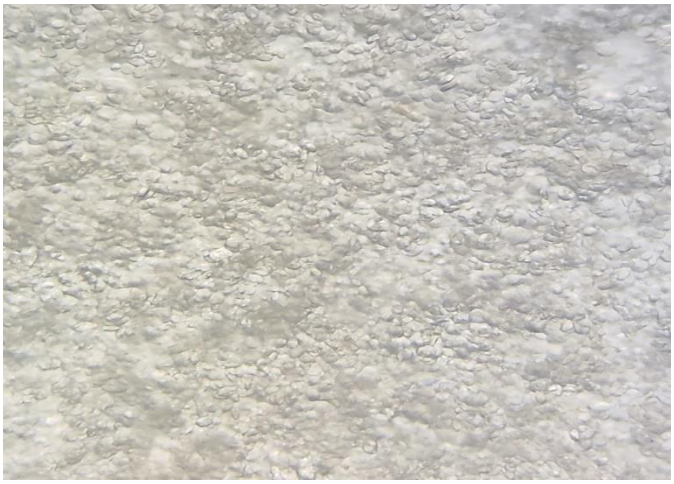

Figure No:-2; microscopic view of *Hordeum vulgare* starch powder

STARCH BASED NATURAL EXCIPIENT

Starch is white tasteless and odourless powder. Starch is insoluble in cold water and alcohol but it is hygroscopic and binds reversibly with water and heating start the gelatinization of starch [10, 11]. The structure of starch can be determined by using either scanning electron microscopy (SEM) or transmission electron microscopy (TEM). Starch synthesized from various parts such as seeds, tubers, roots, grains, etc. This obtained in large amount in wheat, maize, rice, cassava etc. They are widely utilized due to their ability to form viscous solution, films, gel etc. in various pharmaceutical dosage forms. This also low cost, biologic origins, highly caloric and has improved physicochemical properties. But when source differ, then appearance, composition, properties also differ. One of the important properties of starch is the gel formation. This ability of starch widely used in pharmaceutical industry as well as in food industry.

MODIFIED STARCH

Modified starch prepared to improve the physicochemical properties and thereby reducing the limitations occurred by the use of native starch, which include low flow property, poor solubility etc. Modification stabilizes the granules and increases the standards of the tablet formulation. This involves the restructuring of starch granules. Chemical modifications are by substitution, degradation, cross-linking etc. This improves the structural, nutritional and functional properties.

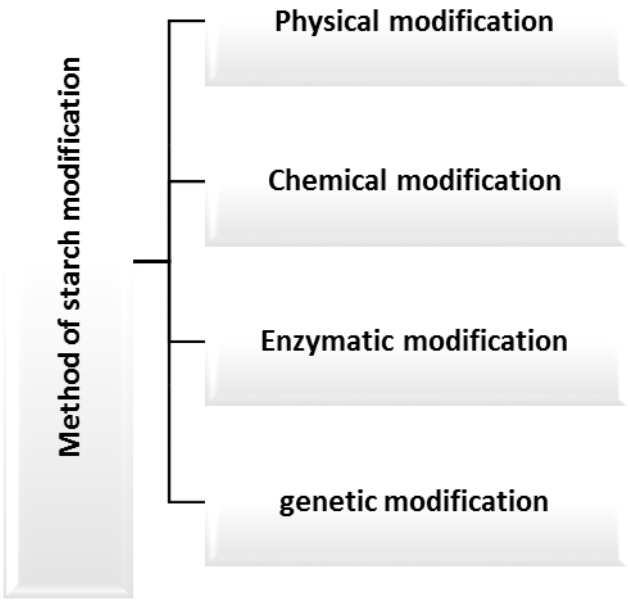

Figure No:-3; Method of starch modification [14].

Pre-gelatinization is a physical modification, which increases the solubility, viscosity and also enhances the flow characters, binding efficiencies thereby increased acceptance. The physical modification is more attractive due to certain reasons such as no chemical usage, environmental protection, the simplicity of process. The pre gelatinized starch can be used as binders in direct compression as well as in wet granulation.

STARCH BINDERS IN WET GRANULATION AND DIRECT COMPRESSION

Wet granulation and direct compression both are important required steps in pharmaceutical manufacturing. The binders are essential in granulation process, so choice of binder is crucial step. It must fulfil some functions like compact binding, suitable flow characteristics of powder, particle size uniformity, disintegration, compatibility with other excipients etc [12, 13].

Starch and its derivatives are excellent polymers for granulation process. The careful selections of binder and granulation process result in best possible granules and tablets.

Binders used in wet granulation are hydrophilic and soluble in water. They dissolved in water and form a wet mass that is finally granulated. A dry binder compresses well and produces cohesive dry blends due to its better adhesive character [15]. In direct compression, it requires only that the drug is properly blended with appropriate excipient before compression process. The direct compression formulations have some advantages such as reduction in

number of steps and cost of production. When modified starches are used achieve minimum cost with desired performance [12,13].

ISOLATION PROCESS OF STARCH

Starch extracted from plant by various isolation process. Generally by wet milling processes in case of grains, here the plant material is grounded in water then the debris is filtered out from slurry, finally starch granules are obtained after centrifugation from the suspension [17,18,19].Starch can be extracted from roots and tubers of some plants also.

Example 1: flow chart of the production process of cassava starch [23].

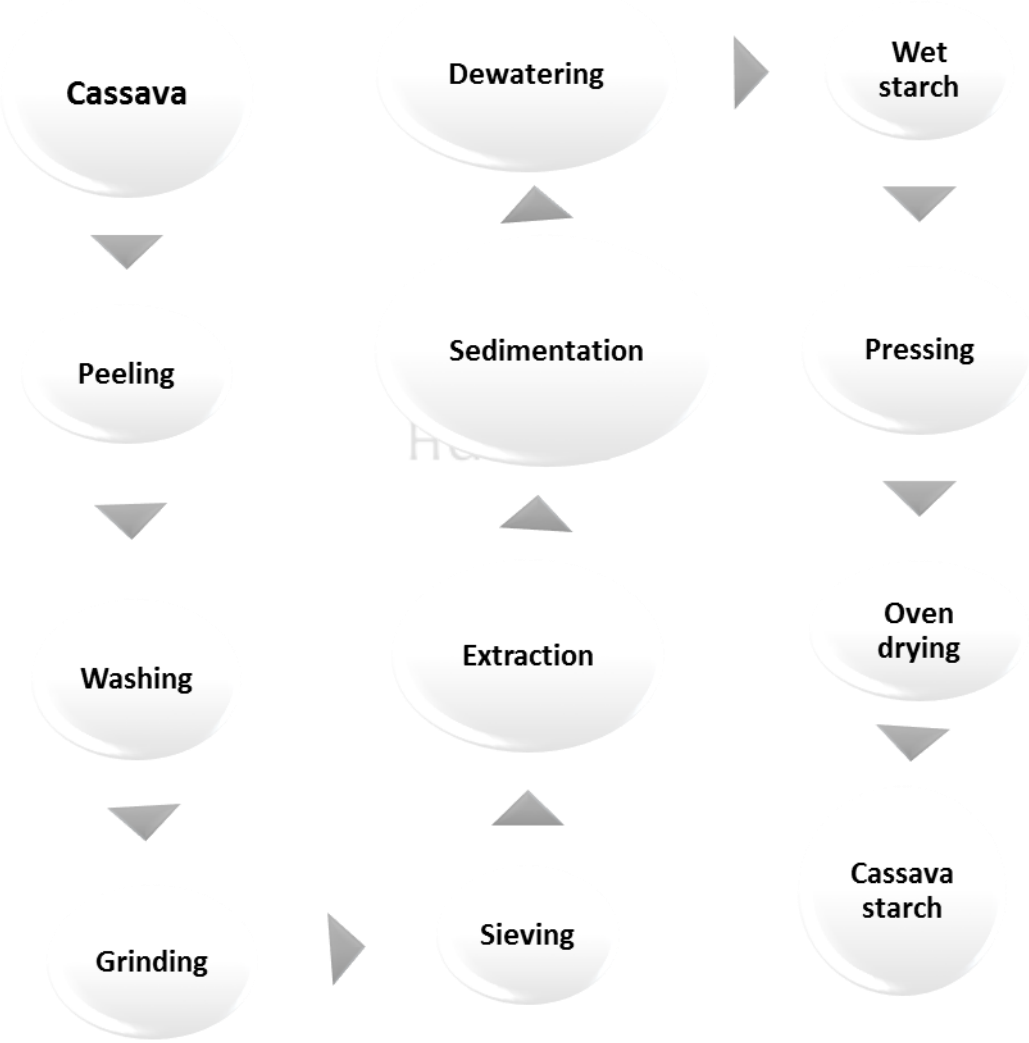

Figure no:-4; Isolation of cassava starch.

Example 2: flow chart of the production process of potato starch.

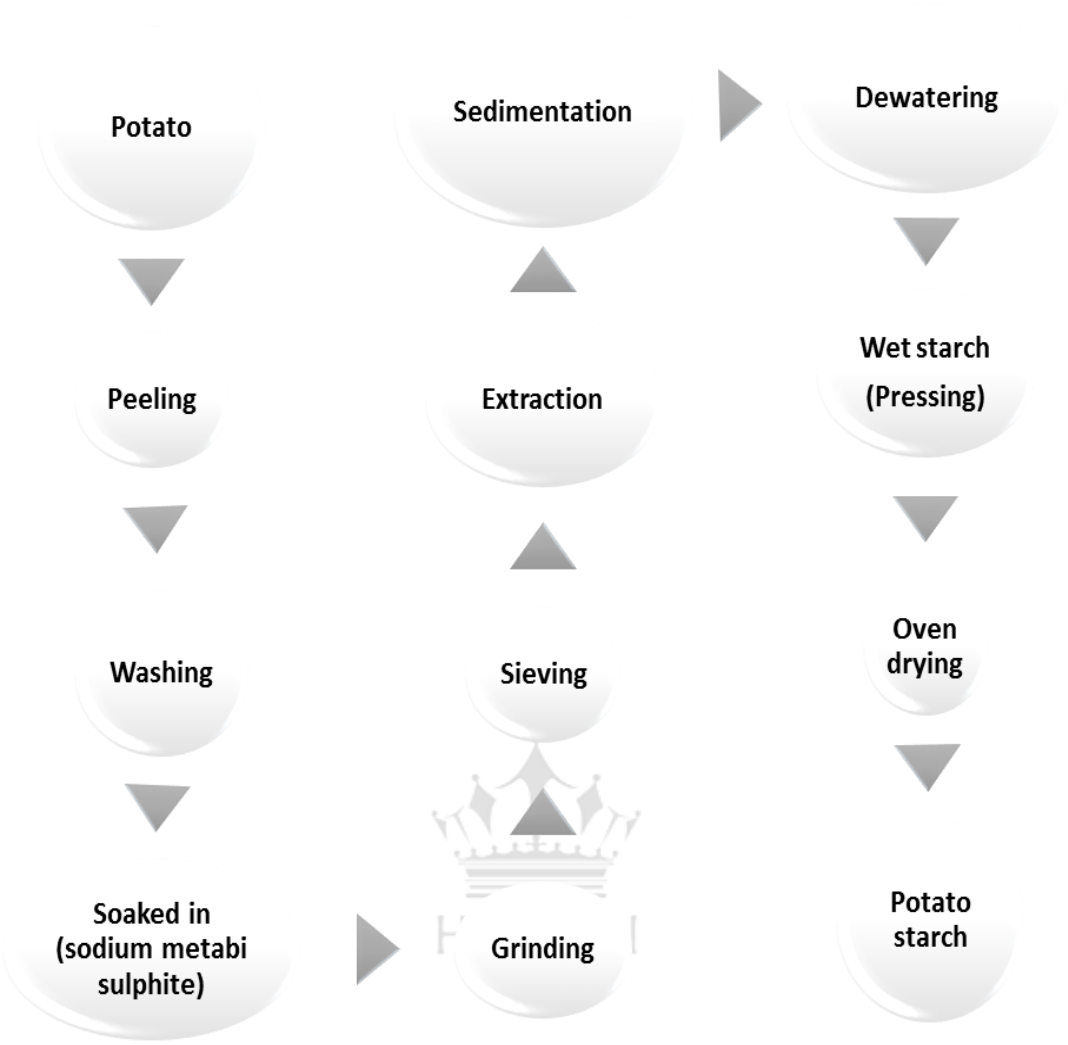

Figure No:-5; Isolation of potato starch.

LIST OF STARCH BASED NATURAL EXCIPIENT

Table No-1; List of starch binders from natural source [11, 16].

SL NO	SOURCE	PLANT PART	BOTANICAL NAME	FAMILY	APPLICATION
1	Banana	Fruit	*Musa paradisiaca, Musa acuminata*	*Musaceae*	Binder, Disintegrant
2	Barley	Cereal grain	*Hordeum vulgare*	*Poaceae*	Binder, Disintegrants
3	cassava	Tuberous root	*Manihot esculenta*	*Euphorbiaceae*	Binder, coating agent, filler
4	Yam	Tubers	*Dioscorea alata*	*Dioscoreaceae*	Binder, Disintegrants
5	Ginger	Rhizomes	*Zingiber officinale*	*Zingiberaceae*	Binder, Disintegrants
6	Maize	Grain	*Zea mays L*	*Gramineae*	Binder, Diluent, Disintegrants
7	Pearl millet	Cereal grain	*Pennisetum glaucum*	*Poaceae*	Binder, Disintegrants
8	Potato	Tuber	*Solanum tuberosum*	*Solanaceae*	Binder, Disintegrants, filler
9	Rice	Cereal grain	*Oryza sativa L*	*Poaceae*	Binder
10	Sorghum	Cereal grain	*Sorghum bicolor*	*Poaceae*	Binder, Disintegrants

PHARMACEUTICALLY RELEVENT PROPERTIES OF STARCH

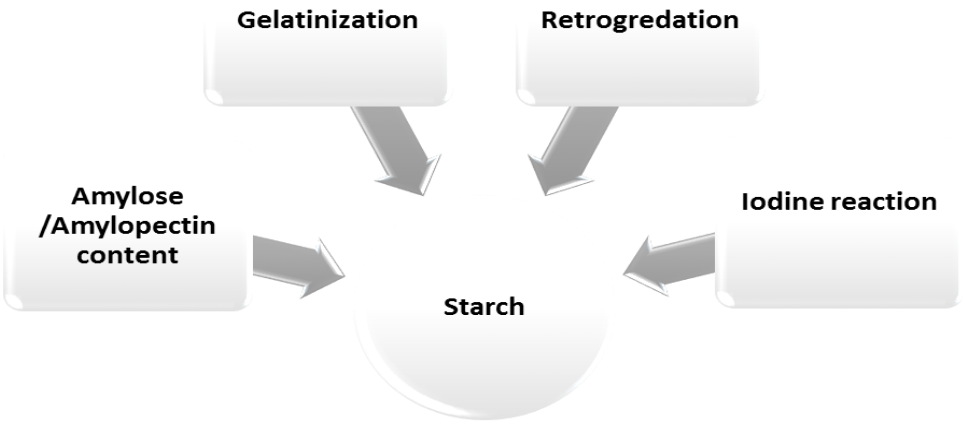

Figure No:-6; general properties of starch as excipients [21].

Amylose / amylopectin content

Starch chemically composed of two polysaccharide units, amylose (amorphous) and amylopectin (crystalline). Amylose /amylopectin content influence the physicochemical properties of starch, so these are major criteria of its functional properties such as swelling and flow property.

Gelatinization

The process in which heating enhances the interaction of granule with water, thereby structural change in amylose and amylopectin, results in granule swelling. The aqueous suspension transform to an amorphous gel phase. The highly viscous gel form improves binding and increase stability [9].

Retro gradation

The retro gradation is the process of reassociation or recrystallization of amylose and amylopectin in gelatinized starch.

Iodine reaction

A purple–black colour produced when the iodine ions inserted into the helical network of amylose chain. It is the important identification test for starch.

PHARMACEUTICAL APPLICATION OF STARCH BASED NATURAL POLYMERS [21].

- **BINDER**

Widely used in the wet granulation process. It is an important step in the production of tablet, capsule, other solid dosage form. Binders improve the flow of API, maintain the consistency, dosage form weight and impart cohesiveness. In wet granulation process starch is used as a liquid binder to create granules.

- **DISINTEGRANT**

Disintegrants is an excipient used in pharmaceutical formulation to achieve the disintegration of solid dosage forms into smaller particle, this facilitates the dissolution and there by the drug release.

- **DILUENT**

Sometimes, drugs which are used at very low doses are difficult to process and compress into tablet and other dosage forms. So, in such cases inert materials are mixed with formulation to increase the bulkiness. Starch is used for this purpose.

- **ABSORBENTS**

Starch can absorb moisture because it is hygroscopic in nature. Therefore, starch can be used as an absorbent in drug formulation to keep powder dry.

- **GLIDENT/LUBRICANT**

Mainly due to their slippery nature, it can be used as lubricant and glidant.

- **OTHER PHARMACEUTICAL PURPOSES**

✓ Production of bioethanol

✓ Excipient in novel drug delivery system (nasal, oral, periodontal).

✓ Taste, flavour, colour, texture enhancement

✓ Skin emollient.

CONCLUSION

Many studies have been conducted in the pharmaceutical field using natural excipients. A variety of plant based pharmaceutical excipients are available today. Now a day the natural binders have excellent demand over their artificial counterparts because all of them are freely available, non-toxic, stable and cost effective [21,22]. Starch is an abundant natural binder with great industrial versatility and commercial value. A variety of modifications or derivatives can be created. So, It is excellent polymer for the wet granulation process matching with all possible formulation and application needs.

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