EXPLORING THE POTENTIAL MAIZE STARCH IN THE DEVELOPMENT OF A NOVEL CO-PROCESSED EXCIPIENT

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Abstract

Starch is the main component of maize, which is produced by wet milling process. Maize starch functionality varies with the starch structure and composition, which vary with genotypes and cultural practices. The average size of maize starch granules ranges between 1 and 7 µm and 15 and 20 µm, respectively, for small- and large-sized granules. Maize relies on humans for its propagation. Since the Columbian exchange, it has become a staple food in many parts of the world, with the total production of maize surpassing that of wheat and rice. Much maize is used for animal feed, whether as grain or as the whole plant, which can either be baled or made into the more palatable silage. Maize starch, derived from corn, has found a significant place in pharmaceutical formulations due to its inherent properties. Its widespread use can be attributed to factors such as cost-effectiveness, stability, and its ability to act as a multifunctional excipient.

Introduction

Minimizing the number of ingredients and processing requirements, these unique excipients enable fast development and reduce manufacturing complexity. Ready-to-use coprocessed excipients are built to simplify every step of the drug development process starting from ideation to go-to-market. sed on monographed excipients Shortens time-to-market with simplified R&D process Streamlines processing via high process consistency and reduced variability Decreases manufacturing complexity (weighing, dispensing, and documentation).

Benefits

- Based on monographed excipients
- Shortens time-to-market with simplified R&D process
- Streamlines processing via high process consistency and reduced variability
- Decreases manufacturing complexity (weighing, dispensing, and documentation)

A very fine, white or slightly yellowish powder or irregular white masses which are readily reducible to powder, creaks when pressed between the fingers, odorless and tasteless.

Maize Starch exhibits all the properties of native starch with some special features such as non-foaming & non-thinning characteristics of boiling solution. Hence maize starch has a marginal effect on the efficiency in weaving and paper industry. Where high viscosity starch is used, it imparts higher tensile strength to the fiber and thus improves the sizing.

ADVANTAGES

- Power house of calories
- Gastric dumping syndrome reliever
- Rashes, burns and itching can be overcome by applying some corn starch on the affected area
- Corn Starch removes excess oil from the skin

APPLICATIONS

- Maize starch is used for its gelling or thickening properties in many sectors of agro-food applications (soups, delicatessen meats, sauces, pastas, creams).
- Used in Pastry, cream, Desserts, coating, etc.
- Sometimes preferred over flour alone because it forms a translucent mixture, rather than an opaque one.

UNIQUE FEATURES

- Flour adjuster (biscuits, cakes)
- Viscosity Reducer
- Ingredient for baby food powder

Starch in Pharmaceutical industry: Functions & Applications

Modified starch is one of the primary raw materials in the pharmaceutical industry owing to its binding, disintegrating and lubricating properties. Starch being a naturally occurring polysaccharide polymeric material, is a storehouse of excess energy and glucose in plants. The pharmaceutical industry uses it as a binder, glidant, disintegrant, diluent and lubricant. Due to its swelling properties, it has its uses as a disintegrant in tablets. It ensures that the tablets and medicines break down easily and dissolve, enabling the drug to release smoothly. As a diluent, it facilitates the effective blending of raw materials during production. Starch has proved to be an efficient dry binder in dry granulation techniques where the active ingredient is hygroscopic and it is difficult to dry after wet binding. Since starch is partial cold water soluble, starch functions exceptionally well in manufacturing tablets by wet granulation applications, it performs dual functions of a disintegrant and a binder. In capsule filling processes, starch functions as an effective binder improving the uniformity of the capsule fill and forming a stable capsule plug. Maize starch was one of the earliest excipients for medicinal dosage due to its non-toxic and non-irritant properties. It is used as an anti-sticking agent in medical products using latex-like surgical gloves, condoms and diaphragms. Furthermore, it also acts as a source of energy and its intake helps prevent low blood sugar. Certain cosmetic products also use dry starch powder as a filler.

Specifications

Compendiu	IP	BP	USP – NF

m Standards			
Identification A, B, C	Complies	Complies	Complies
pH	Not Applicable	4.0 to 7.0	5.0 to 8.0
Acidity	Complies	Not Given	Not Given
Oxidising Substances	Complies	NMT 20 ppm	NMT 0.002%
Sulphated Ash, %	NMT 0.6	NMT 0.6	NMT 0.5
Loss on drying, %	NMT 15	NMT 15	NMT 14
Sulphur di-oxide	Not Given	NMT 50 ppm	NMT 0.008%
Iron	Not Given	NMT 10 ppm	NMT 0.002%
Microbial Limits:			
Total aerobic microbial count, cfu/g	NMT 100 #	NMT 100 #	NMT 100 #
Total yeast and mold count, cfu/g	NMT 20 #	NMT 20 #	NMT 20 #
Pseudomonas Aeruginosa	Absent in a 10g Sample	Absent in a 10g Sample	Absent in a 10g Sample
Escherichia Coli	Absent in a 10g Sample	Absent in a 10g Sample	Absent in a 10g Sample
Staphylococcus Aureus	Absent in a 10g Sample	Absent in a 10g Sample	Absent in a 10g Sample

Salmonella Species	Absent in a 10g Sample	Absent in a 10g Sample	Absent in a 10g Sample

Carbohydrates are the most abundant class of organic compounds in living systems accomplishing various and major roles, from energy production and building blocks of biologic structures to raw materials for food and paper. Last four decades added more sophisticated applications showing the potential of starch, cellulose, chitosan and alginates in drug delivery where their contribution and functionality are continuously growing and diversifying. From simple inactive excipients, new and highly specific compounds with advanced features (i.e. affinity for nonimmune proteins or glycoproteins, stimuli responsive, etc.) are now emerging. This chapter tries to underline how the self-assembling operates in different starch-based excipients making them multifunctional materials. Structural aspects are presented in relation with their key role in self-assembling following starch modifications induced by physical or chemical procedures. The article integrates also examples and discussions on formulation, processing and characterization of self-assembled starch-based drug delivery systems aiming to offer a practical tool to scientists working in the pharmaceutical field.

Maize starch was one of the earliest used excipients for pharmaceutical dosage forms. Depending on the application, maize starch acts as a diluent, disintegrating agent or binder.

We supply different grades of maize starch: regular maize starch, low moisture maize starch and white maize starch. White maize starches differ in their zeaxanthin content, resulting in improved whiteness of the starch. Depending on the application, and the relative importance of the visual appearance of the final product, either one may be chosen.

Roll-dried, pregelatinized maize starch is used as a binding agent in the granulation of active ingredients. More recent developments suggest selected pregelatinized starches are excellent bioadhesives and can be used as a matrix for slow release.

Maize Starches

These starches are suitable to be used as an Excipient (EXC).

C☆PharmGel® acts as a hydrophilic polymer that gelatinizes when heated in an aqueous environment, forming a smooth gel with excellent binding properties. C☆PharmGel® is compatible and can be mixed with most excipients and drugs.

Brand:

- C☆PharmGel®
- C☆PharmGel® 03406 (regular corn based) & 03302 (white corn based) have received CDE filing in China

Functionalities:

- Disintegrant
- Diluent
- Binder (after cooking in water)

Applications:

- Solid dosage formulations
    - Diluent in direct compression and wet and dry granulation
    - Diluent in capsule and powder formulations
    - Disintegrating agent for tablet porosity, at 3-15% dosage
    - Binder for wet granulation (cooked)
- Topical formulations

Pregelatinized maize starches

Brand:

- C☆PharmGel®

Functionalities:

- Binder
- Diluent

Applications:

- Solid dosage formulations
    - Diluent/binder in direct compression and wet and dry granulation
    - Diluent in capsule and powder formulations
    - Slow release tablet formulations

Starch Properties

- Starch exists as a white-colored powder at room temperature and pressure.
- On heating, starch decomposes and doesn't undergo melting or boiling.
- The autoignition temperature of starch is around 683 K.
- The density of starch varies greatly.
- It is insoluble in cold water and alcohol.

Maize starch is used for its gelling or thickening properties in many sectors of agro-food applications (soups, delicatessen meats, sauces, pastas, creams). Used in Pastry, cream, Desserts, coating, etc. Sometimes preferred over flour alone because it forms a translucent mixture, rather than an opaque one.

Maize starch is a traditional excipient used in pharmaceutical and nutraceutical products to act as a binder, disintegrant, or diluent. It's often used in solid dosage forms like tablets, capsules, blends, granules, and pellets:

- Native starch: A classic disintegrant for tablets
- Pregelatinized starch: Often used as a binder
- Oxidized maize starch: A disintegrant filler and binder that can be used in a variety of dosage forms

Maize starch is used because it's bland, odorless, and digestible. Different grades of maize starch are available, including regular, low moisture, and white. Amylomaize and waxy maize starches have a specific amylose amylopectin ratio that gives them different behaviors compared to other maize starches, but they still offer the same stability. The demands on the functionality of excipients are increasing day by day because of the emergence of high-speed tableting machines and the use of direct

compression methods for tableting. Co-processing plays an important role in the development of a stable excipient with multifunctional activity. The combinations of one or two natural or synthetic polymers have been explored widely to develop novel stable co-processed excipients. In recent years, the co-processing of plant-based components has proved to be a boon for large no of pharmaceutical industries worldwide. The current review article highlights the general description of co-processing, techniques employed, and advantages of using natural components in co-processing. Also, the recent developments in excipient technology with special emphasis on natural combinations that could be used as co-processed excipients are briefly discussed.

Conclusion

The various factors responsible for the development of co-processed excipients includes more attracted direct compression method towards pharmaceutical companies and need for ideal filler binder is increasing at an alarming rate. Also, the ability to adjust the solubility, permeability, stability of drug molecules. It is necessary to compensate for the poor mechanical properties and low aqueous solubility of emerging active ingredients. Starch and modified starches are safe and well established excipients. It can be physically modified to enhance its properties and to improve its performances. It can also be chemically modified to obtain a very wide range of new properties that can play an important role in the formulation of complex delivery systems. In today's pharmaceutical industry, excipients must have more functional properties than being just inert filler. Excipients are now essential parts of the drug delivery system in pharmaceutical tablets. They are generally used as diluent, binder, disintegrant, gliding agent, lubricant or release control agent. At a time when synthetic polymers and animal-based products are creating some concerns amongst the users, the need for natural excipients that are safe and versatile becomes more acute. Starch is widely used as a binder in the wet granulation process of massing and screening which is an important step in the production of tablets, capsules, and other solid dosage forms. The granulation process is used to improve the flow of APIs which tend to be very cohesive.

References

1. *Amol Main & Bhairav, Bhushan & Saudager, R.. (2017). Co Processed Excipients for Tabletting: Review Article. Research Journal of Pharmacy and Technology. 10. 2427. 10.5958/0974-360X.2017.00429.2.*
2. *Bordoloi, B. J., Kalita, B., & Shil, D. (2019). Properties, Pharmaceutical Application And Various Technique Of Chemical Modification In Native Starch: A Descriptive Review. International Journal Of Current Pharmaceutical Research.*
3. *Guth, Felicitas & Schiffter, Heiko & Kolter, Karl. (2013). Novel excipients-from concept to launch. Chimica Oggi/Chemistry Today. 31. 78-81.*
4. *Jain, Sajal & Kaur, Simrandeep & Rathi, Ritu & Nagaich, Dr. Upendra & Singh, Inderbir. (2023). Application of co-processed excipients for developing fast disintegrating tablets: A review. Polymers in Medicine. 53. 10.17219/pim/158009.*
5. *Kaushik, D., Goel, E., Verma, R., Pandey, P., Purohit, D., Mittal, V., Kumar, K., & Habibur Rahman, M. (2021). An Overview of Recent Patents and Patented Technology Platforms based on Co-processed Excipients. Recent patents on drug delivery & formulation.*
6. *Liew, K.B., Hii, S.H., Chew, Y., Ming, L.C., Uddin, A.H., & Sarker, Z.I. (2022). Application of Co-processed Excipient as a*

Novel Method to Compound Orally Disintegrating Tablets. International journal of pharmaceutical compounding, 26 3, 255-263.

7. *LENAERTS, V. et al.; "Cross-linked high amylose starch use in controlled release formulation and processes for its manufacture; US 09/606,399, 2000*
8. *BOUCKAERT, S. et al.; J. Pharm. Pharmacol. 1993, 45, 504-507*
9. *BOUCKAERT, S. et al. Eur. J. Clin. Pharmacol. 1993, 44, 331-335*
10. *REMON, J.P. et al., "Starch based drug delivery systems"; Symposium Chemical Aspects of Drug Delivery Systems, Salford University, April 17-18, 1996*