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Tablet Binders as an Excipient in Pharmaceutical Formulation: A Review of Their Functionality and Factors to be Considered

Kaviyarasan. K*[1]

*[1] M. Pharm, Department of Pharmaceutics. School of Pharmacy, Sathyabama Institute of Science and Technology, Chennai – 600119, Tamilnadu, India.

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ABSTRACT:
Binders in the tablet formulation strengthen the inter-particulate bond power within the tablet. The development of innovative accessories for possible usage as a binder in tablet formulations continues to be a top goal. The materials that are added, either dry or liquid, during wet granulation to create granules or tablets are known as tablet binder or binding agent. to encourage tablets that are immediately squeezed to form cohesive compacts. For instance, sorbitol, PEG, starch, pregelatinized starch, HPMC, etc. A tablet In an oral solid formulation, the opposite is true for binder and disintegrants. While disintegrant accelerates tablet breakdown, binder delays it. By keeping all of the constituents (API and excipients) together in any solid dosage form, they are essential in ensuring that pellets, granules, and tablets maintain their shape until they achieve their goal. Choosing the right binder is essential to preserving the tablet's integrity. Natural binders, like because a variety of starches, gums, mucous, and dried fruits, among other substances, can bond. Features like natural fillers, disintegrants, and polymers are safer and less expensive than synthetic ones.

INTRODUCTION:

Today's dosage forms are often complicated systems with numerous additional components in addition to the active pharmaceutical ingredient (API). These compounds are typically added in conjunction with the active pharmaceutical ingredients to maintain, protect, or improve the formulation's stability. Both drugs are present in drug goods. compounds (also known as excipients or active pharmaceutical ingredients, or APIs). The excipients selected, their concentration, and their interactions have a direct impact on the drug product's final biological, chemical, and physical characteristics. Delivering the medication to the patient in the necessary quantity, at the requisite pace, consistently within a batch, from batch to batch, and throughout the product's shelf life is the aim of a medicinal formulation development project. The constituents of a formulation, like those in a tablet, are held together by binder excipients. Tablets, powders, granules, and other materials can be created with the necessary mechanical strength thanks to binders. Additionally, they deliver tablets with low active doses volume. The binder excipient's function is to serve as a binder to hold together powder, granules, and other dry components to provide the product with the required mechanical strength. They can also provide medications in little doses. using a binder to produce more efficient and consistent particle production, typically utilized for wet granulation. In a process known as granulation, these excipients have the ability to aggregate powders into granules and modify their flow, strength, solubility, compaction, and drug release. Drug manufacturing uses binder excipients.

Classification of Binders

Natural:

These are less toxicity, biodegradable, availability at low cost. Examples include starch, pregelatinized starch, Sodium alginate, and gelatin, etc.

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Synthetic/ Semisynthetic:
These are the most widely used and required a low amount in a formulation. Examples include Polyvinyl Pyrrolidone (PVP), Methylcellulose, Hydroxy Propyl Methyl Cellulose (HPMC), Polymethacrylates, Sodium Carboxy Methyl Cellulose, Polyethylene Glycol (PEG) and Methylcellulose, etc.

Saccharides and their derivatives:
Disaccharides such as lactose and sucrose; Polysaccharides and their derivatives such as starches, cellulose or modified cellulose such as MCC and cellulose ethers such as hydroxypropyl cellulose (HPC); Sugar derivatives such as sorbitol, xylitol, and mannitol, etc.

Classification Based on their application in the manufacturing process
Dry tablet binders:
These are included into the powder mixture either as part of a direct compression (DC) formula or following a wet granulation process. Cellulose, Polyvinylpyrrolidone (PVP), Hydroxy Propyl Methyl Cellulose (HPMC), Sodium CarboxyMethyl Cellulose, and Polyethylene Glycol (PEG) are a few types of dry tablet binders. as well as methylcellulose.
Solution tablet binders:
Wet granulation processes make advantage of them. These are dissolved in an alternative solvent, like isopropyl alcohol or water. Cellulose, gelatin, cellulose derivatives, polyvinyl pyrrolidone, starch, sucrose, mannitol, polyethylene glycol, and liquid glucose are a few examples of solution tablet binders.
Natural Binders
- Starch
- Natural gums
- Dried fruits

Starch as binders:
A variety of natural polymers, such as gums, starches, and pre-gelatinized starches, are utilized as binding agents. Although starches such as rice, maize, potato, wheat, and corn are widely known for their ability to bind and disintegrate, other starches, such as enset and banana starches, can also be utilized as binding agents. Another application for starch is as a filler. In many food applications, starch serves as a thickening, stabilizing, gelling, and/or filling ingredient. It is also one of the most often used excipients in medicinal formulations. It is mostly utilized as a disintegrant, binder, or filler in tablets. Granules of starch are the main source of carbohydrates in plant tubers and seed endosperm. It mostly comprises two kinds of polymer molecules: a significant number of mostly linear amylase molecules (usually 20–30%) and several million highly branched amylopectin molecules (about 70–80%). One of the most common excipients utilized in the production of solid dosage forms is starch. Starches derived from various Both the mucilage and the dry powdered form of these sources have been tested and found to be excellent binders. Researchers have attempted to create botanical starches for use as tablet excipients, despite the fact that maize starch is the most commonly utilized excipient in tableting. Researchers have looked into how the starches in plantains and pigeon peas affect the compressional, mechanical, and disintegration characteristics of paracetamol tablets.
Using Starch 1500 as a binder
When compared to Lamivudine tablets made with povidone, Starch 1500 worked as a great binder, creating a compressible granulation that resulted in tablets with increased hardness and friability.
The way Lamivudine is made Tablets containing Starch 1500 outperformed the povidone formulation that used a super disintegrant in terms of dissolving and disintegration. By decreasing the tablets' wet ability as determined by the adhesion tension of water, the kind and quantity of binders were discovered to change the rates of dissolution and disintegration. Producing granules with a consistent (and reproducible) distribution of medication particles within the bulk carrier (excipient) solid is the goal of pharmaceutical granulation. This can be challenging to accomplish, as granule enrichment and drug depletion are both possible outcomes. It was discovered that tapioca starch, a natural substance, was used as a binding agent in the manufacture of Diclofenac tablets. Potato starch and

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maize starch were chosen and prepared for comparison in order to establish two additional frequently used disintegration agents. The three disintegrants mentioned above were used to create several formulations at a dosage of 20 mg per tablet. They were made using the wet granulation method.

Natural gum and mucilage as binder High molecular weight carbohydrates are the building blocks of the majority of natural polymers, such as gum and mucilage. They are non-hazardous, biodegradable, and biocompatible polymers with erratic physical-chemical characteristics and environmentally friendly traits. The most prevalent biological compounds are carbohydrates, which span a wide range of essential functions in living organisms, including the storage and transportation of energy (starch and glycogen), the formation of structural elements (cellulose in plants, chitin in animals), and the hemicellulose that connects intercellular barriers. Polysaccharides are the high molecular weight carbohydrates that are produced. They can be thought of as condensation polymers, where water molecules have been removed and carbohydrates have been connected via glycosidic bonding. n $C_6H_{12}O_6 \rightarrow (C_6H_{10}O_5)_n + (n-1)H_2O$

The wide range of polysaccharide physical and biological applications can be attributed to their distinct macromolecular architectures and chemical compositions. A variety of polysaccharides, including agar, alginate, chitin, and pectin, can hydrate in both hot and cold water to form gels and viscous solutions or dispersions. The The gelling qualities of these polysaccharides are the only reason for their high interest in aquatic animal feed.

Ideal Properties of Binders

- Physiologically inert.
- Acceptable to regulatory agencies.
- Physiologically and chemically stable.
- Should not interfere with the bioavailability of the drug.
- Commercially available in a stable form.
- Meet the standards of regulatory requirements

Name of Tablet Binder	Concentration (%)
Acacia	1.0 – 5.0
Copovidone	2.0 – 5.0 (In direct compression) 2.0 – 5.0 (In wet granulation)
Carbomer	0.75 – 3.0
Corn Starch and Pregelatinized Starch	Commercially known as STARCH 1500
Calcium carboxymethylcellulose; calcium cellulose glycolate; carmellosum calcium	5.0–15.0
Carboxymethylcellulose Sodium, Carmellose Sodium	1.0–6.0
Ceratonia	0.15 – 0.75
Chitosan Hydrochloride	Chitosan is a well-known polysaccharide
Dextrates	Purified mixture of saccharides
Dextrin	Low-molecular-weight carbohydrates
Ethylcellulose	Ethylcellulose being blended dry or wet granulated with a solvent such as ethanol (95%)
Liquid Glucose	5.0 – 10.0
Guar Galactomannan,/ Guar Gum	Up to 10.0
Hydroxyethyl Cellulose	Derived from cellulose
Hydroxyethylmethyl Cellulose	Derived from cellulose
Hydroxypropyl Cellulose	2.0 – 6.0
Low-Substituted Hydroxypropyl Cellulose	Most widely used

Table: 1 - List of Tablet Binder used in Pharmaceutical Preparations

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Advantages

Because of their low toxicity, availability, biodegradability, and affordability, natural polysaccharides are frequently employed as excipients and additives in the food and pharmaceutical industries.

Additionally, they can be utilized to alter the drug's release, which will affect its absorption and subsequent bioavailability of the integrated medication.

They can be applied to alter drug release, which affects the integrated medication's absorption and bioavailability.

Because of their low toxicity, biodegradability, affordability, and accessibility, natural binders are widely utilized as excipients and additives in the food and pharmaceutical industries.

Dis- Advantages

- Polymers binder can lead to processing problems such as rapid over granulation, tablet hardness increases & dissolution concert diminish.
- In case of polymer binders, addition of strong disintegrates usually required but these are huge expensive and have a negative effect on product stability.
- Includes several processing steps
- Usage of various solvents may lead to drug degradation
- Enhances the hardness of the granule
- Application of heat might degrade the thermolabile therapeutic agent

Binders Evaluation Test

There are numerous factors that affect the quality of granules These can be caused by variable process as well as the formulation, which should be constantly evaluated and monitored to determine the suitability for the tableting. Characteristics that affect the quality of granules include:

Physical and chemical stability
Efficacy
Compactness
Fast production capability
Particle Size and Distribution

The disintegration time, average tablet weight, variance, granule friability, wet granulation drying rate kinetics, and granulation flowability are all impacted by granule size. The granule size and distribution are influenced by the tablet's quality, which is decided by the formulator. Microscopy, sieving, and the conductivity test are frequently used assays for size and distributions.

Tablet Surface Area:

The surface area of the medications is assessed, usually during dissolution, in some situations where they have restricted water solubility. Typical techniques include gas adsorption and air permeability.

Density:

Higher compression loads are required for thick and hard granules in order to speed up medication dissolution and tablet disintegration. Typically, a pyrometer is used to measure density. The tablet's porosity, flow characteristics, dissolving, and compressibility can all be impacted by its bulk, granule, and actual densities.

Friability:

To Friability is important as it affects the size distribution of the granules which in turn affects the compressibility, weight variation and granule Flowability. It is measured via the Tumbler Test or the Friability Test/Roche Friabilator and the % loss is determined.

Moisture Content:

The moisture content affects the compressibility, flowability and the stability of moisture sensitive drugs and as such should be determined in order to check the granulator's quality.

Factors to be considered

Compatibility:

Compatibility of the binder with other components is very important. The Differential Scanning Calorimetry can be used to determine compatibility.

Drug characteristics:

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Characteristics such as size, porosity, compressibility, solubility and hydrophobicity can affect the process. Drugs that have poor compressibility would require strong binders whereas porous ones would need a high level of liquid binder. Drugs that have high absorption rate would require higher volume of binder.

Spreading of the Binder:

Spreading the binder together with the powder blend is another important factor; an excellent binder is one that can be easily spread (e.g. HPMC).

Binder Quality and Type:

The uniformity of the tablet's features depends on the quality of the binder added to the formulation. A high concentration of binder can cause hard granulation, whilst insufficient quantity of the binder would result to fragile granulation. Large quantities of granulating liquid can cause coarse and hard granules. In order to ensure that variations are limited and uniformity is reached, the quantity of the liquid added should be prepared and measured beforehand.

Granulator Construction Materials:

The type of construction material affects the volume of the binder and the granule size being distributed. Vessel walls that are wetted easily by binders would require a high volume of binders; for example, stainless steel vessels would require higher binder volume than vessels that are made of plastics such as PMMA or Teflon. The use of PMMA or PTFE would narrow the particle size distribution due to the high contact angle whereby all liquids are forced directly to the powder bed. With stainless steel, this is different: less contact angle liquid layer is formed in the wall surface, causing inhomogeneous distribution of the liquid over the powder bed, resulting in broader granules.

Granulator Type:

Fluidized bed granulators produce porous granules unlike those produced by the High Shear granulator.

Impeller Movement:

Wet mass sticks to the vessel less if the impeller movement is helical, resulting in fewer lumps and narrow granule size. This is usually a problem when using the High Shear Mixers because wet mass sticks to the vessel; coating the vessel with polytetrafluoroethylene can reduce this problem. The correct construction of the impeller must also be observed.

CONCLUSION:

Numerous natural polymers have been used in pharmaceutical formulations. Natural substances including gum, dried fruits, mucilage, and starch can be used as a binding agent. Along with other properties like disintegration agents, fillers, and maintain release agents, they have shown great potential as binding agents. Polymers showed excellent binding qualities in wet granulation, producing granules that are less friable and more stable than those made with other binders. Numerous natural polymers have been included in medicinal formulations. Gums, mucilage's and dried fruits are examples of natural materials that can be utilized as binding agents.

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