Review Article

Starch as Pharmaceutical Excipient

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ABSTRACT

It is very well known that none of pharmaceutical preparations either for internal or external use can be manufactured without excipients. Excipient is defined as any substance other than active drug or pro-drug that is included in the manufacturing process or is contained in finished pharmaceutical dosage forms. Selecting best excipients, however, requiring a balance between time and cost efficiencies as well as anticipated product performance. Starch is one of the traditional excipients used in the manufacture of tablets. Chemically, starches are polysaccharides, composed of a number of monosaccharides or sugar (glucose) molecules linked together with α-d-(1-4) and/or α-d-(1-6) linkages. Starch has been investigated as an excipient in novel drug delivery systems for nasal, oral, periodontal, and other site-specific delivery systems. Depending on the application, specific starches are available for use as disintegrants, fillers or binders. As a result of its partial cold water solubility, starch functions exceptionally well in tablet manufacture by wet granulation applications and performs dual functions of both a disintegrant and a binder. In capsule filling processes, Starch and Star Cap Co-Processed Starch Excipients function as effective binders. As a result of its partial cold water solubility, starch functions exceptionally well in tablet manufacture by wet granulation applications and performs dual functions of both a disintegrant and a binder. In capsule filling processes, Starch function as effective binders. Starch is also one of the most commonly used tablet disintegrants at concentrations of 3–15% w/w. However, unmodified starch does not compress well and tends to increase tablet friability and capping if used in high concentrations. As a diluent, starch is used to facilitate subsequent mixing or blending processes in manufacturing operations.

Keywords: Starch, Binder, Disintegrants, Diluent.

INTRODUCTION

According to the international pharmaceutical excipient council, Excipient is defined as "Any substance other than active drug or pro-drug that is included in the manufacturing process or is contained in finished pharmaceutical dosage forms". The US pharmacopoeia-National formulary (USPNF) categorizes excipients according to the functions they perform in the formulations e.g. Binders, disintegrants etc[1]. Choosing the right excipients can make all the difference in the efficient production of robust tablets. Pharmaceutical formulators are seeking ways to improve the manufacturing process and product quality through the use of functional excipients. Selecting the best excipients, however, is a juggling act, requiring a balance between time and cost efficiencies as well as anticipated product performance.

Excipients are pharmaceutical additives, the inactive ingredients used to make up a medication. They include dyes, flavors, binders, emollients, fillers, lubricants, preservatives, and many more classifications. Common excipients used as fillers include corn starch, lactose and Dibasic Calcium phosphate dehydrate.[1,2]

Starch is one of the most abundant natural carbohydrates stored in plants. It is found in many different plant organs including seeds, fruits, tubers and roots, functioned as a source of energy. Although starch is widespread, abundantly available, cheap, degradable, pollution-free and renewable, it has many short falls, i.e., insoluble in cold water, easy to dehydration, low emulsifying power and unstable in acid, due to which commercial application is limited.[3] A survey of the literature shows that the usefulness of starches from various botanical sources as pharmaceutical excipients. Starches are widely available and have been very useful in tablet production due to their inertness, cheapness and utilization as fillers, binders, disintegrants and glidants. [4]

Chemically, starches are polysaccharides, composed of a number of monosaccharides or sugar (glucose) molecules linked together with α-d-(1-4) and/or α-d-(1-6) linkages. Starch consists of 2 main structural components, the amylose, which is essentially a linear polymer in which glucose residues are α-d-(1-4) linked typically constituting 15–20% of starch, and amylopectin, which is a larger branched molecule with α-d-(1-4) and α-d-(1-6) linkages and a major component of starch. Amylose is linear or slightly branched with a degree of polymerization up to 6000, and has a molecular mass of 105–106 g/mol. The chains can easily form single or double helices. Amylopectin on the other hand, has a molecular mass of 107–109 g/mol. It is highly branched and has an average degree of polymerization of 2 million, making it one of the largest molecules in nature. Chain lengths of 20–25