Starch GRAS listed. Included in the FDA Inactive Ingredients Database (buccal tablets, oral capsules, powders, suspensions and tablets; topical preparations; and vaginal tablets). Included in nonparenteral medicines licensed in the UK. Included in the Canadian Natural Health Products Ingredients Database.

Pregelatinized starch Included in the FDA Inactive Ingredients Database (oral capsules, suspensions, and tablets; vaginal preparations). Included in nonparenteral medicines licensed in the UK.

Coprocessed corn starch and pregelatinized starch is included in nonparenteral medicines licensed in the UK, and has been included in approved drug products in the EU, Latin America and Asia.[2]

17 Related Substances

Starch; Starch, Pregelatinized.

18 Comments

Corn starch has undergone harmonization for many attributes for JP, PhEur, and USP-NF by the Pharmacopeial Discussion Group. For further information see the General Chapter 5.8 in PhEur, along with the 'State of Work' document on the PhEur EDQM website, and also the General Information Chapter G10 in the JP.

StarCap 1500 is a free-flowing, low-dust excipient with disintegration and dissolution properties independent of medium pH, which help promote deaggregation of the powder mass into primary drug particles and speeds up the dissolution rate of the drug substance, providing rapid disintegration across the pH range present in the human digestive tract.[3–5] *StarCap 1500* has been used in studies to determine the influence of disintegrants on the release rate of theophylline.[6] The coprocessed product has been designed specifically for use in capsules and directly compressed tablets, and has enhanced physical properties that cannot be achieved by single blend. It has been reported as having excellent properties for high-dose, high-solubility capsule formulations, with low weight and good content uniformity.[3] The product acts as a compression aid, diluent, and disintegrant, which allows for robust but simple capsule and directly compressible tablet formulations.

19 Specific References

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21 Author

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22 Date of Revision

6 April 2017.

Corn Syrup Solids

1 Nonproprietary Names

PhEur: Glucose Liquid Spray-Dried

USP–NF: Corn Syrup Solids

2 Synonyms

Dehydrated hydrolyzed starch syrup; dried glucose syrup; glucosum liquidum dispersione desiccatum; *Maltrin*; soluble corn fiber; resistant maltodextrin.

3 Chemical Name and CAS Registry Number

Corn syrup solids [68131-37-3]

4 Empirical Formula and Molecular Weight

$(C_6H_{10}O_5)_nH_2O$ $\leq 4\,000$

Corn syrup solids are mixtures of amylose (D-glucose units connected by 1→4 glycosidic bonds) and to a lesser extent, amylopectin (D-glucose units connected by 1→4 glycosidic bonds and branched chains connected by 1→6 glycosidic bonds).

The relative amounts of monosaccharides, disaccharides, trisaccharides, and polysaccharides depend on the process used for starch hydrolysis. Dextrose Equivalence (DE) is a quantitative measure of the degree of starch polymer hydrolysis. It is a measure of reducing power compared to a dextrose standard of 100. Products with higher DE have a greater extent of starch hydrolysis. As the product is further hydrolyzed (higher DE), the average molecular weight decreases and the carbohydrate profile changes accordingly.