

Chapter I

Introduction

Suspensions are heterogeneous system consisting of two phases. The continuous or external phase is generally a liquid or semisolid, and the dispersed or internal phase is made up of particulate matters that is essentially insoluble in, but dispersed throughout, the continuous phase. Traditionally, certain kinds of pharmaceutical suspension have been separated designation, such as mucilages, magmas, gels, and sometime aerosols; also included dry powder to which a vehicle is added at the time of dispensing (Patel, Kennon and Levinsion, 1986). Many drugs are too unstable (either physically or chemically) in an aqueous medium to allow aqueous liquid formulation as solutions, suspensions, or emulsions. Instead, the drug is formulated as a dry powder that is reconstituted by addition of water. The reconstituted product is usually an aqueous solution; however, occasionally it may be an aqueous suspension (Hempenstall et al., 1985).

Starch is multipurpose excipient used in tablet formulation which can be used as filler, a binder (Tasana Pitaksuteepong, 1995), a disintegrant (Thavisak Teruya, 1995) or a lubricant depending on its type, concentration, modification and methods of incorporation. However, native starch has its limitation in application (Banker, Peck and Baley, 1980). The introduction of modified starches and starch derivatives has enhanced the research attempts in pharmaceutical preparation to overcome the problems that occurred from the limit use of starch. Unlike the native starch, modified starches and starch derivatives possess several characteristics that allow them to be employed more extensively as ingredients in drug formulation than native starch. Starch derivatives were used as crosslinking agents in preparations of microcapsules. These characteristics, including the improvement in flowing, compressing, and disintegrating properties, have been investigated to evaluate modified starches and starch derivatives as a binder and disintegrant (Visavarungroj, Herman, and Remon, 1990a; Visavarungroj, Herman and Remon 1990b).

The properties of chemically modified starches or physically modified

starches are depended on the modification method and the control of condition while the modification takes place. The properties of starch are also depended on the ratio of amylose/amylopectin which varies among different plant species and sources. This leads to the attempts of modifying various natural starches in order to obtain compounds that possess appropriate properties as suspending agent.

Sodium carboxymethyl starch is one of the modified starches which provide cold-water solubility and viscosity. Because of these properties of these chemically modified starch, it is interested to study the use of sodium carboxymethyl starch as a binder in tablet formulation (Filbert, 1952; Robert, 1967) or as suspending agent in dry syrup formulation. In the most recent work, Tasana Pitaksuteepong (1995) studied the properties of five modified starches including rice starch, glutinous rice starch, tapioca starch, corn starch, and potato starch as tablet binder. The result of the study revealed that glutinous rice starch possessed the best binding property among all five modified starches being investigated.

Ornanong Suwannapakul (1996) prepared sodium carboxymethyl starch in three different degrees of substitution (DS) based on Filbert's method (Filbert, 1952). Four domestically available starches, including tapioca starch, rice starch, glutinous rice starch and corn starch were chemically modified and evaluated for their properties as suspending agent. Suspending property of modified starches was evaluated in terms of viscosity, ease of redispersion and sedimentation volume. As a result, suitable modified starches being selected were modified glutinous rice starch (MGS), modified rice starch (MRS) and modified tapioca starch (MTS) with degree of substitutions of 0.16, 0.26 and 0.38, respectively.

This study is a consequent research of the works mentioned above. The purpose of the study is focused on the evaluation of modified starches as suspending agent. Three domestically available starches, including glutinous rice starch, rice starch and tapioca starch were chemically modified by the substitution reaction with carboxymethyl group to each degrees of substitution based on Ornanong's results (Ornanong Suwannapakul, 1996). These modified starches were examined and evaluated for their suspending properties. Selected modified starches were employed as suspending agent in a development of dry syrup formulation using amoxicillin and cephalixin as model drugs.

Objectives of this study

1. To modify a number of domestically available natural starches by the substitution reaction with carboxymethyl group in order to obtain an appropriate sodium carboxymethyl starch with suitable properties to be used as suspending agent in dry syrup formulation
2. To compare the suspending properties between the prepared modified starches and commercially available suspending agents Ultrasperse®2000 when used in dry syrup formulation



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