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Coating potential of a new modified starch coating for immediate release oral tablets

Tareq A. Rumman, Israa H. Al-Ani, Samira F. Hassan

Abstract Film coating of tablets is the application of a thin layer of coating material to improve the tablet properties. Different coating materials like hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA) have been widely used in tablet coatings for immediate release of the active pharmaceutical ingredient. A new immediate release film coating formula that contains modified corn starch as the coating polymer was investigated, and it shows improved physiochemical properties over conventional film coating material (HPMC and PVA). The purpose of this study is to investigate the potential of the new modified starch coating as a coating material in comparison with HPMC- and PVA-based formulas. Evaluation was done on a coating powder dispersion of 20% w/w by measuring the viscosity, sedimentation, foaming behavior, and microbial stability. Free films were prepared from each coating formula and tested for water vapor permeability and morphology. The coating process was then executed on the model tablets (levofloxacin 500 mg) after optimizing the coating parameters. Characterization of modified starch film-coated tablets was done by testing morphology, hardness, friability, thickness, disintegration, and drug release profiles. It was concluded that the new modified starch coating is superior to HPMC and PVA formulations in terms of free film and applied coated tablet esthetics, inner structure composition, preparation and coating process parameters. Additionally, the modified starch coating showed similar release profiles to HPMC- and PVA-based coating formulas.

Keywords Film coating, Modified starch coating, Immediate release, Hydroxypropyl methylcellulose, Polyvinyl alcohol

T. A. Rumman, I. H. Al-Ani (✉), S. F. Hassan
Faculty of Pharmacy and Medical Sciences, Al-Ahliyya Amman University, Amman 19328, Jordan
e-mail: dr_issra@yahoo.com

Introduction

Tablets have been coated for nearly 150 years, beginning with sugar coating and evolving to film coatings in the 1980s. Coatings have played a significant role in adding benefits, but also cost to the production of tablets. Different coating types and processes play a crucial role in the physiochemical, mechanical, and drug release properties of tablets, which is directly related to the desired need behind their coating. Coatings can improve the esthetic qualities of tablets, mask unpleasant tastes and odors, allow the product to be more easily swallowed, facilitate handling (particularly high-speed filling and packaging), improve tablet stability, and modify the drug release characteristics.[1]

Film coating is now the most commonly used tablet coating method, and is mainly used for hard compressed tablets along with other applications in the nutrition and food industries. The popularity of film coating, compared with sugar coating, is thanks to some significant advantages. Tablets with a film coating usually weigh up to 5% more than the uncoated tablet, in comparison with the enormous weight gained with sugar coating that might reach 50%.[2] Coating formulations consist of specific material mixtures that play a crucial role in modifying film properties. Examples of such materials are polymers (natural or synthetic), solvents, plasticizers, and colorants. Polymers form films that cover the tablet with a layer 20–100-μm thick, and are divided into either immediate release polymers or enteric polymers.[3,4]

Polymers used in aqueous-based coatings of solid dosage forms are divided into water-soluble polymers, pH-dependent (enteric coating) polymers, and water insoluble (sustained release) polymers. Hydrophilic coating polymers are the most commonly used polymers because they dissolve completely in the gastrointestinal tract and do not modify the drug release characteristics of the dosage forms. Examples are