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Development of Probiotic Formulations Containing Shellac

S. STUMMER, S. SALAR-BEHZADI, H. VIERNSTEIN

Department of Pharmaceutical Technology and Biopharmaceutics, University of Vienna, Althanstraße 14, 1090 Vienna, Austria

E-mails: stefanie.stummer@univie.ac.at (S. Stummer), sharareh.salar-behzadi@univie.ac.at (S. Salar-Behzadi)

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Probiotic microorganisms have been shown to provide specific health benefits when consumed as food supplements or as food components. The main problem of such products is the poor survival of the probiotic bacteria in the low pH of gastric fluid. However the use of synthetic excipients for enteric coating to prevent the exposure of microorganisms to gastric fluid is limited in food supplementary industry. Therefore the aim of this study was to develop an enteric coating formulation containing shellac as a natural polymer. Shellac possesses good resistance to gastric juice; the major disadvantage of this polymer is its low solubility in the intestinal fluid [1, 2]. Thus films containing different ratios of shellac and water-soluble polymers (sodium alginate, hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidone (PVP)) or plasticizers (glycerol and glyceryl triacetate (GTA)) were prepared in order to analyse the films' melting temperatures (T_m), the changes in enthalpy (ΔH), their capability of taking up water, and their solubility in different media. The release characteristics of the films were studied by loading pellets with *Enterococcus faecium* M74 and coating them with formulations containing different amounts of shellac and polymer or plasticized shellac. Using dissolution tests, performed according to USP XXXI paddle method, the resistance of the coatings to simulated gastric fluid (SGF, pH 1.2) and the release of cells in simulated intestinal fluid (SIF, pH 6.8) was investigated.

The trials showed that an increasing amount of plasticizer results in a decrease of T_m and ΔH of the films whereat glycerol had a superior plasticization effect to GTA. The compatibility of films made of water-soluble polymers and shellac was also concentration dependent. HPMC and PVP showed superior compatibility with shellac compared to sodium alginate, since films containing shellac and more than 10% [w/w] sodium alginate tended to separate into two phases. In the end five formulations containing shellac and either 5% [w/w] glycerol, 10% [w/w] PVP, 20% [w/w] PVP, 10% [w/w] HPMC, or 5% [w/w] sodium alginate emerged as feasible for enteric coating purposes.

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