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Natural Polymers as Excipients for Formulation Development

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Recently, supplementaries containing probiotic microorganisms are getting more and more important. Due to the fact that synthetic excipients are limited in the preparation of nutritional supplements, an increasing trend for using excipients from natural sources can be noticed. Therefore, the investigation of the coating properties of shellac - as a natural polymer - and the development of probiotic enteric coating formulations containing shellac were of interest in the current study. Shellac possesses good resistance to gastric fluid. The major problem of this polymer is its low solubility in the intestinal fluid [1, 2]. In order to improve the enteric properties of shellac, sodium alginate, hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidon (PVP) were chosen as additional water-soluble polymers and glycerol and glyceryl triacetate (GTA) as plasticizers. Films with different concentrations of shellac, polymer and plasticizer were provided. The films were analysed concerning their melting temperature, swelling rate and solubility in different media. The probiotic microorganism *Enterococcus faecium M74* was coated with different formulations containing shellac and water-soluble polymers or plasticized shellac. The resistance of coatings to simulated gastric fluid (SGF) and the release of microorganisms in simulated intestinal fluid (SIF) were investigated by dissolution tests, performed according to USP XXX paddle method.

Films consisting of 100% [w/w] shellac were brittle, with a melting temperature of 73.87±1.58 °C, they were insoluble in acidic pH and less soluble in alkali pH. Glycerol had a superior plasticization effect to GTA and increasing the concentration of this additive in the films resulted in significant changes in the thermodynamic properties of these films. The compatibility of water-soluble polymers with shellac was also related to their concentration and miscibility with shellac. HPMC and PVP showed superior compatibility with shellac compared to sodium alginate. The addition of 5% [w/w] glycerol or 10% [w/w] PVP to shellac resulted in a good protection of microorganisms against SGF and an optimal release profile in SIF.

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[2] Limmatvapirat S, Limmatvapirat C, Puttipipatkhachorn S, Nuntanid J, Luangtana-anan M. Enhanced enteric properties and stability of shellac films through composite salts formation. Eur J Pharm Biopharm. 2007; 67: 690–698. doi:10.1016/j.ejpb.2007.04.008