Physical Properties of Films Containing Shellac

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The use of the synthetic excipients commonly applied in the pharmaceutical industry is limited in the preparation of nutritional supplements. Consequently, there is an increasing trend to use excipients from natural sources for preparation of supplementaries. The aim of the current study was the investigation of the coating properties of shellac as a natural polymer on the one hand, and development of enteric coating formulations containing shellac for protection of the probiotic microorganisms against the low pH of gastric juice on the other.

Films with different amounts of shellac (Marcoat 125®, Syntapharm, Germany), polymer and plasticizer have been provided. The polymers used were HPMC (Syntapharm, Germany) and sodium alginate (FMC, USA). The Tg values of the films (n=3) were investigated using a differential scanning calorimeter (micro DSC III, Setaram Instrumentations, France). The weight loss and the water uptake of the films (n=3) were also measured upon exposure to buffer solutions with pH of 1.2 for 2h and pH 6.8 for 3h in a horizontal shaker (Inova4000, Brunswick sciences, USA) at 37±0.5°C. Thereafter, pellets (Pharmatrans Sanaq, Switzerland) loaded with *Enterococcus faecium* M74 (Medipharm, Sweden) were coated with formulations containing different amounts of shellac and polymer. The survival of uncoated versus encapsulated cells in simulated gastric fluid (SGF, pH 1.2) was examined (n=3) by dissolution tests performed according to USP XXVIII, paddle method for 2 h at 37±0.5°C, 100 rpm and with 200 ml of SGF. In order to estimate the release of cells in simulated intestinal fluid (SIF, pH 6.8), the formulations were further exposed to 200 ml SIF for 3 h using the paddle method as described above.

Addition of plasticizer to the shellac films resulted in a decrease of the Tg of the films. The films containing shellac and Na-alginate in different ratios were almost insoluble in pH 1.2. Increase of Na-alginate in the films resulted in the raise of swelling rate in pH 1.2 and the raise of the solubility in pH 6.8. Otherwise, increase of HPMC in the films resulted in the raise of the solubility of films in both pH 1.2 and 6.8. The swelling rate of films containing HPMC was higher than films containing Na-alginate after exposure to pH 6.8. It is concluded that using formulations containing shellac and up to 25% (w/w) Na-alginate should provide enough resistance against SGF and optimal release of micro-organisms in the SIF. However, the best result was achieved by using formulations consisting of shellac, HPMC and plasticizer in the ratio of 70%, 17% and 13% (w/w) respectively.