

New Coating Materials Based on Mixtures of Shellac and Pectin for Pharmaceutical Products

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Abstract : Shellac is a natural polyester resin secreted by insects. Pectins are natural, non-toxic and water-soluble polysaccharides extracted from the peels of citrus fruits or the leftovers of apples. Both polymers are allowed for the use in the pharmaceutical industry and as a food additive. SSB Aquagold® is the aqueous solution of shellac and can be used for a coating process as an enteric or controlled drug release polymer. In this study, tablets containing 10 mg methylene blue as a model drug were prepared with a rotary press. Those tablets were coated with mixtures of shellac and one of the pectin different types (i.e. CU 201, CU 501, CU 701 and CU 020) mostly in a 2:1 ratio or with pure shellac in a small scale fluidized bed apparatus. A stable, simple and reproducible three-stage coating process was successfully developed. The drug contents of the coated tablets were determined using UV-VIS spectrophotometer. The characterization of the surface and the film thickness were performed with the scanning electron microscopy (SEM) and the light microscopy. Release studies were performed in a dissolution apparatus with a basket. Most of the formulations were enteric coated. The dissolution profiles showed a delayed or sustained release with a lagtime of at least 4 h. Dissolution profiles of coated tablets with pure shellac had a very long lagtime ranging from 13 to 17.5 h and the slopes were quite high. The duration of the lagtime and the slope of the dissolution profiles could be adjusted by adding the proper type of pectin to the shellac formulation and by variation of the coating amount. In order to apply a coating formulation as a colon delivery system, the prepared film should be resistant against gastric fluid for at least 2 h and against intestinal fluid for 4-6 h. The required delay time was gained with most of the shellac-pectin polymer mixtures. The release profiles were fitted with the modified model of the Korsmeyer-Peppas equation and the Hixson-Crowell model. A correlation coefficient (R^2) > 0.99 was obtained by Korsmeyer-Peppas equation.

Keywords : shellac, pectin, coating, fluidized bed, release, colon delivery system, kinetic, SEM, methylene blue

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