

Abstract

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Tablet coating represents an important procedure in pharmaceutical technology. The coating can protect an active pharmaceutical ingredient from negative environmental conditions as well as ensure the drug release at a specific time and a specific site in the organism. Generally, the main types of tablet coating are sugar and film coating. As the sugar coating has a number of disadvantages such as a time-consuming production process, the difficult process standardization, the impossibility to produce a modified release mechanism, is nowadays rarely being used in pharmaceutical companies. This work deals with the replacement of sugar coating with film coating technology for the multivitamin product Spofavit®. During the pilot batch, the commercial coating mixture Nutrafacient® Food Supplement Coating, Opadry AMB was applied on two types of tablet cores: the original composition tablet cores and the modified ones with added lactose. The weight variation, hardness, friability and disintegration properties were tested. After processing the results of the pilot batch, a scale-up from the pilot to the production scale for the original composition tablet cores was performed with the utilisation of a Glatt Coater 1500 coating machine. The resulting film coated tablets showed good stability and disintegration properties. Once the manufacturer fulfils the necessary legal requirements, Spofavit® film coated tablets will be ready for sale on the Czech market and the routine production.