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Dry powder coating in a modified wurster apparatus

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Abstract

The results of dry coating of pharmaceutical materials (micro-particles), carried out in spout-fluid bed apparatus, designed by the authors are presented in the paper. The design has been developed starting from the Wurster conception device. The examination consisted of the determination of the optimal composition of coating mixture-powder to plasticizer proportion, as well as the determination of basic process parameters (flow rates of individual streams). Resistance of coating on the conditions in gastrointestinal tract was chosen as optimization criterion. The purpose of the process is to defend an active substance placed in a core from the surroundings in the stomach. This active substance should be excellent dissolved only just in the small intestine (in case of an intestine medicine application).

Keywords: Spout-fluid bed; dry powder coating; wurster apparatus

Nomenclature

c	methylene blue concentration	(mg/l)
t	time	(s)

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1. Introduction

Coating means putting an envelope on a core of tablet (microparticle) and it is commonly applied in pharmaceutical, food and chemical industries. Many times, this process is decisive in creating the needed properties of the commercial product [1].

The cores could be coated by the use of a sugar envelope, mainly saccharose (pills) or by multi-molecular substances possessing coating abilities (coated tablets). Applying coating, it is possible to protect active component from the activity of atmospheric agents (oxygen, carbon dioxide, light and humidity). It is also possible to get esthetic look and at the same time to mask odorous smell and taste of the active substances.

The coating protects the carrier from the loss of volatile components, that exist in it. It is also possible to get the effect of controllable dissolution of a medicine, in determined position of gastrointestinal tract (tablets dissolved in the gut), applying coating with the substances, which solubility depend on the pH in the environment [2].

The oral medicines with prolonged activity are used to assure constant, sufficiently high concentration of active substance in a human organism, for a long time e.g. 24 h [3]. The most important, in such an instance, is obtaining practically, a retarded absorption, by lowering the release speed of an active substance from the medicine. Coating enables, in that case, the separation of the initializing and sustaining doses actions. Sustaining dose is placed in the core of a medicine tablet and coated with an envelope, which is not dissolved in the gastric acid. The outer layer of the medicine tablet consists of a coat, which contains initializing dose, which dissolves in an acid medium. According to that, initializing dose is released immediately in the stomach and the sustaining dose acts only, after envelope dissolving, in the small intestine. The active substance could be released from the core once or in relevant periods of time.

The main disadvantage of classical film coating methods with the use of water, which supplant organic solvents, is high concentration of water in the final product. In the case of coating of medicines or other biologically active products, humidity could cause the product destruction or its inactivation [4]. In connection with that, it is necessary to dry the product gently for a long time, which increases the costs and lengthens the time of the whole process [2]. The solutions and suspensions of the coating substance possess high viscosity, which could cause both clogging of the nozzle and an agglomeration of the coating particles [5].

The solution of those problems is the dry coating method, in which the application of whatever liquids is completely or partially eliminated. Since nineties of XX century, different methods of dry coating have been investigated, considering their possibility of an application in the pharmaceutical industry. Although there has been potential possibility of those methods application, only few have been implemented in the industry [2, 6].

The basic disadvantage of those methods is comparatively a large loss of a valuable coating substance, which is blown away in the case of the fluidized-bed apparatus application. Unfortunately, the coating substance separated in a gas-solids separator could not be used again, because of its contamination by the plasticizer.

Among many known devices applied for particles coating, a spout-fluid bed apparatus, with a spraying nozzle located at the lower part of a bed are considered as an optimal construction [1]. There is great chance of solid particles collision with droplets of coating solution in that system, high process efficiency and short drying time. But there is also great risk of the bed agglomeration, just above the nozzle, because of high concentration of the wet particles [7]. Certain modification of this design is Wurster apparatus [8]. Wurster apparatus is constituted by a spouted bed apparatus with a draft tube and an additional air stream