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Film coated floating tablets using sublimable substances

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During the past few decades floating drug delivery systems (FDDSs) have been developed to prolong gastric retention time and obtain sufficient drug bioavailability [1]. To avoid unpredictable time to float due to variable pH of the gastric fluid in each subject and food in the stomach [2], sublimation technique is the new interesting approach to prepare non-effervescent FDDSs [3]. The objective of the present study was to develop the low-density film coated floating tablets using sublimable substances.

To prepare low density porous core tablets, model drug (anhydrous theophylline), filler (e.g., microcrystalline cellulose, HPMC), and sublimable substance (ammonium carbonate) were mixed for 10 min prior to addition of magnesium stearate (0.5% w/w) and Aerosil®200 (0.5% w/w). The powder mixture was further mixed for 3 min and compressed into tablets (diameter, 9.53 mm; biconvex; hardness, 9–10 kg; average tablet weight, 300 mg) using a single punch tableting machine (Model YH06, Yeo Heng Co., Ltd., Thailand). The tablets were incubated at 70 °C for 72 h to eliminate sublimable substance. The porous tablets were coated with Eudragit® RL 30D plasticized with 20% w/w diethyl phthalate. Coating condition is as follows: batch size, 1 kg; preheating temperature, 50 °C; preheating time, 30 min; inlet temperature, 48–50 °C; outlet temperature, 39–41 °C; atomizing air pressure, 2.5 bar; spray rate, 5–8 mL/min.

The results exhibited that addition and increasing level of sublimable substance increased porosity of core tablet, leading to reduction of density and hardness of the tablet. Although the porous core tablets could float immediately, the floating time of the core was quite short. Therefore, the polymeric

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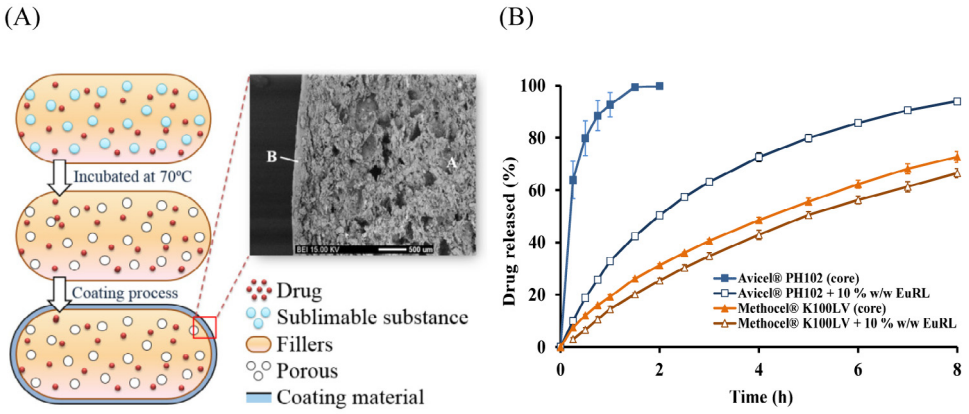

Fig. 1 – Schematic and SEM photomicrograph of a cross-section of film coated floating tablets (40% w/w ammonium carbonate, 10% w/w Eudragit® RL30D) (A) and drug release profiles (B).

membrane was needed. The SEM photomicrograph of a cross-section of film coated floating tablets demonstrates the porous structure of the core tablet coated with Eudragit® RL30D film (Fig. 1). The film coated floating tablets using sublimable substance could initially float due to low-density of the systems (<1 g/cm^3) and maintain floatation more than 8 h with sustained drug release as required in this study. Eudragit®RL30D coating might not only plays a role to control the drug release, but also entrap air in the porous structure of the core tablet and maintain low density of the system.

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