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Title : NEW MODULES AND ASSEMBLED SYSTEMS FOR THE CONTROLLED RELEASE OF DRUGS IN COMBINATION

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Dome Matrix technology is a platform for the controlled release of drug. This technology is based on the assembling of modules used as elements for controlling the drug release. The research project of the doctorate thesis was devoted to the application of Dome Matrix technology for the preparation of gastro-retentive dosage forms thanks to the module assembly in void configuration. According to the co-tutorship agreement, the research was carried out both at University of Parma and University Teknologi MARA, Kuala Lumpur. During the first part of the project, carried out at University of Parma, a modular assembled system for a double pulse release (immediate and delayed release) of esomeprazole in combination with sucralfate was studied. The assembled system was build up by assembling 5 modules, three sucralfate modules and two esomeprazole modules, in "mixed" configuration (void and stacked configurations) with three different release kinetics. The alkalizing agent in the esomeprazole immediate release module prevented the degradation of the drug in acid environment in vitro. The role of alkalizing agent in preventing the degradation of the drug in acid environment was further investigated via permeation studies and in-vivo pharmacokinetics studies on rats. The second pulse was obtained via the partial coating of one esomeprazole module and its assembly in void configuration with a sucralfate controlled release module. During the second part of the project, carried out at UiTM (Kuala Lumpur), a floating dosage form for the controlled release of norfloxacin was developed. The control of drug release was determined by the in situ cross-linkage of alginate with calcium iones when in contact with gastric fluid. The floating of the dosage form was confirmed in vivo using Dome Matrix assembled system loaded with barium sulphate. The floating of the Dome Matrix assembled system *in vivo* led to an increased bioavailability of the drug compared to the conventional non-gastroretentive tablets that was confirmed via pharmacokinetic studies on rats.