methacrylate derivatized pullulan(GMA-pullulan)was synthesized by coupling of GMA to pullulan in the presence of 4-(N,N-dimethylamino)pyridine using DMSO as an apretic solvent and characterized by FTIR. Cholic acid is one of the major bile acids. Bile acid is the main product of cholesterol metabolism and biologically the most detergent-like molecules in the body. Since bile acid can self-associate in water and form micelles, it is expected that the amine-terminated GMA-pullulan(GMAP) modified by cholic acid also self-associates to form core-shell structures. In this study, we synthesized cholic acid/amine-terminated GMAP, and prepared core-shell type nanospheres by diafiltration method.

[PE1-20] [10/19/2000 (Thr) 15:00 - 16:00 / [Hall B]]

Effects of adhesives and permeation enhancers on the skin permeation of cisapride

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A transdermal delivery system containing cisapride was developed as a drug-in-adhesive type patches. Effects of the adhesives and permeation enhancers on the skin permeation of cisapride from the prepared patches were evaluated using Frnaz diffusion cells fitted with excised rat skins. To increase the solubility of cisapride in the adhesives, oleic acid was selected as a solubilizer. The permeation rate of the drug through the excised rat skins was dependent on the type of polyacrylate copolymers studied, and Duro-Tak 4098 was showed the highest permeation rate of the drug. Among the permeation enhancers employed, oleyl alcohol resulted in pronounced enhancing effect on the skin permeation of the drug. From these results, we could suggest that the drug-in-adhesive type patch of cisapride may be feasible.

[PE1-21] [10/19/2000 (Thr) 15:00 - 16:00 / [Hall B]]

in vitro Evaluation of Generic Drugs (II) - comparative dissolution test

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In order to be authorized as therapeutic drugs for new drugs or equivalent, materials of bioequivalency test have to be submitted for the review on their safety and efficacy. Whereas generic drugs and drugs on official compendium are waived for submission of those materials. Since not only physical properties such as solubility, particle size, polymorphism, but the additives, manufacturing process are known to influence on the dissolution profiles of active ingredients of dosage forms, comparative dissolution tests are considered as a major mean to predict the bioavailabilities between drug products. Even though similarities in the dissolution profiles does not guarantee the bioequivalancy, most of the oral dosage forms are considered as bioequivalent if their dissolution profiles are similar in various dissolution conditions.
In this study, we intended to examine the dissolution profiles of generic brand and suggest the method of comparative dissolution test for assurance of similar therapeutic effect. Morphine sulfate sustained release tablets and codeine phosphate tablets were compared for dissolution profiles. The brand name products were used as control products whereas generic products were used as test products. After three different lots of brand name products were tested in four different dissolution conditions (test solutions - water, pH 1.2, pH 4.0 or pH 6.8 , 900mL, 50rpm, paddle method), we found that all of test products showed the similar dissolution profiles from control products and fell into the acceptable criteria in our dissolution specification. To secure the qualities of drugs in which the dissolution test does not specified in the drug test method, it is recommended to have more studies on the dissolution tests for the surveillance purpose.