

The normal penile length($18\pm 5\text{mm}$) was increased to $39\pm 8\text{mm}$ after application of intraurethral solution, which was similar to that after intracavernosal injection 1g of PGE1($38\pm 6\text{mm}$). Duration of erectile response of intraurethral solution($287\pm 34\text{min}$), however, was much longer than that of control ($32\pm 8\text{min}$). Histological examination revealed no or very little irritancy. Conclusions. PGE1 intraurethral solution for erectile dysfunction could be developed employing feline erection model.

[PE1-25] [04/19/2001 (Thr) 15:30 - 16:30 / Hall 4]

The investigation on adhesive properties of an anti-inflammatory plaster containing ketoprofen

Choi YG, Kim JJ, Sim YC

Pacific R&D center, Pharmaceutical & Health Institute, 314-1, Bora-ri Kiheung-eup, Yonhin-si, Kyounggi-do, 449-900

This study was conducted to get the available information that could be applied into development of a drug-in-adhesive (DIA) type plaster containing ketoprofen (KP). When an anti-inflammatory DIA type plaster is developed, we should consider several properties such as drug absorption, drug stability, skin irritation, appearance, and adhesion on skin. Because plasters are applied on skin for long time (above 12 h), adhesive property is very important factor in DIA-plaster formulation. Actually, main patient's discontent on commercial products is that plasters do not show acceptable adhesive property as good as a patient is satisfied. Therefore, it is required to develop a plaster with reasonable skin adhesion. DIA-type plaster has an adhesive-layer consisted of adhesive and additives such as drug and enhancers, etc. These additives usually convert original PSA property to unwanted direction. Thus, it is difficult to control the adhesive property of an adhesive-layer. Additionally, even if same adhesive-layer formulation is applied to various backings, one final plaster adhesive property is different with one another. In this study, adhesive properties of each DIA formulation containing KP were observed according to the combination of an acrylic adhesive, KP, penetration enhancers, and backings. The adhesive property of a formulation was evaluated by in-vitro test such as 180o peel adhesion, ball tack, and shear test.

[PE1-26] [04/19/2001 (Thr) 15:30 - 16:30 / Hall 4]

Evaluation of Disintegration Test of Soft Capsules

Choi MS, Jang SJ, Kang CS, Choi BK, Park SH, Park SA, Kang MH^o, Hong JH, Kim KS *

Department of Drug Evaluation, KFDA

The crosslinking process in gelatin causes formation of a swollen, rubbery, water insoluble gelatin resulting in increasing disintegration time. The effect of crosslinking and disintegration medium on dissolution time and the effect of disintegration apparatus on disintegration of soft capsules exceeding 20.0 mm in diameter were studied.

Soft capsules were filled with three solutions of aqueous formaldehyde in PEG(0.05, 0.3, 0.5 %), stored at ambient conditions for 96 hr, emptied, disintegration tested scanned in NIR spectrophotometer. The more increased concentration of formaldehyde, the more increased disintegration time in water, KP disintegration medium I and USP simulated gastric fluid. But in USP simulated gastric fluid, the differences of disintegration time among crosslinking amounts were less than in water.

In the case of marketed samples, the differences of disintegration time among test mediums were not different and accepted by KP disintegration test criteria.

We conducted disintegration test with KP apparatus and USP apparatus B in the soft capsules of which diameter was over 20.0 mm. The disintegration time between KP apparatus and USP apparatus