Formulation optimization of a new bioadhesive film for dermal/transdermal drug delivery

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PURPOSE

The aim of this work was to optimize the formulation of the transdermal bioadhesive film named Patch-non-Patch® (1,2). This system is a polymeric film, flexible, water permeable, electrically conductive, not self-adhesive but only when applied on wet skin, obtained from a solution/suspension of a film forming agent, an adhesive and a plasticizer. In particular we investigated the mechanical properties, the in vitro transdermal penetration and the in vivo skin accumulation of a model drug (lidocaine) as a function of the composition of the film.

METHODS

Mechanical properties

- Tensile strength (T.S.) and elongation at break (E.B.) (3)
- Dynamometer (Acquisti, Milan, I)
- 5 kg load cell
- Film strip: 20x100 mm
- Rate: 30 mm/min

Permeation studies

- Franz type diffusion cells (0.6 cm²)
- Rabbit ear skin
- Receptor: saline solution
- Donor: Patch-non-Patch

Stratum corneum distribution

- 4 volunteers (age range 24-30)
- Patch-non-Patch, Luan gel
- Application time: 30 min
- Tape stripping (15 times)
- Lidocaine extraction (1 ml CHCl₃: p44 phosphate buffer (20:80, v/v), 45°C, 30 min)

RESULTS

Mechanical properties (placebo)

- Effect of PVA molecular weight
- Effect of drug loading
- Effect of adhesive
- Effect of plasticizer

Permeation studies

- In vivo adhesion

In vivo studies

- Stratum corneum concentration profile
- Comparison with commercial gel
- Effect of water
- Effect of Iontophoresis

CONCLUSIONS

The addition of a plasticizer to the formulation is essential to improve the mechanical characteristics of the film. Lidocaine permeation across rabbit ear skin from dermal patches follows Higuchi’s kinetics. The choice of the adhesive seems to be an important variable governing drug transport from transdermal film. Patch-non-Patch® is more effective than commercial formulation in accumulating lidocaine in the stratum corneum. Iontophoresis increases in a significant way the amount of lidocaine accumulated in the stratum corneum.

REFERENCES