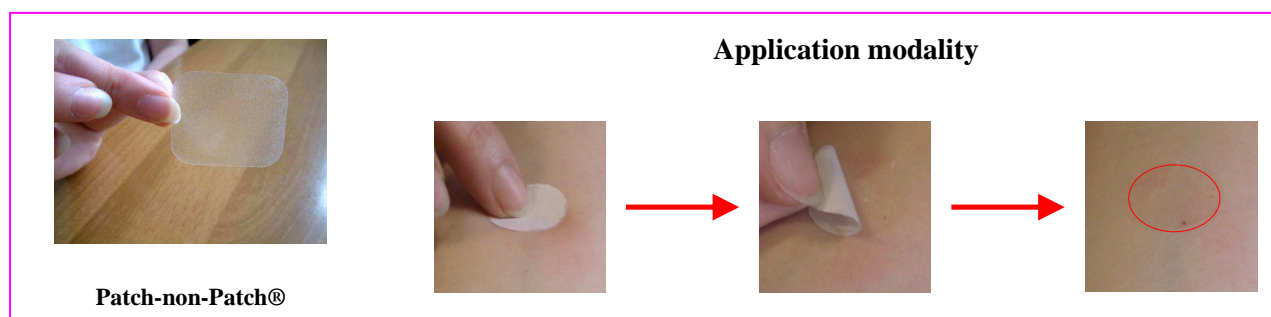


Bioadhesive film for dermal and transdermal drug administration

Prof. Patrizia Santi – University of Parma – Consorzio TEFARCO Innova

Transdermal drug administration represents a valid alternative to traditional administration routes. Existing transdermal drug delivery systems (patches) have still some limitations, such as skin irritation and visibility when applied on the skin. Additionally, existing patches show low efficiency since only a small percentage (10 %) of drug loaded reaches the body. Hence, there is still the need of new transdermal drug delivery systems (patches) able to overcome the limitations of the existing ones.

The aim of the research is the realization of an innovative therapeutic system, characterized by a monolayer structure, composed of advanced materials. The system developed is a bioadhesive film to be applied on the skin after wetting with water.



1. Description of the product

This research is aimed to the realization of an innovative therapeutic system, characterized by a monolayer structure, composed of advanced materials. The system developed is a bioadhesive film to be applied on the skin after wetting with water. The film is thin, transparent and water permeable and delivers high percentages of active contained (up to 50%).

The materials used for its preparation are advanced, characterized by their complete biocompatibility. No organic solvents are required, to reduce the environmental impact.

2. Innovative aspects of the product

The project is based on a patent that describes the realization of a film for transdermal drug administration. The bioadhesive film realized is not adhesive by itself but only when applied on wet skin, can be easily removed with or without water and releases a high percentage of the drug included.

The product of this research project is meant for pharmaceutical, cosmetic and medical industries.

The realization of a transdermal therapeutic system, able to guarantee better performances compared to the existing ones, is a need of pharmaceutical companies, considered the success but also the limitations of existing products. In the last years, some cosmetic companies are using cosmetic patches among their innovative products, using technologies and materials already well known. Finally, medical companies have patches, to be used on wounds or after surgery, in their portfolio.

In general, companies producing patches are highly specialized ones, contract manufacturers for pharmaceutical, cosmetic and medical companies. Those producing companies will be involved for the development of fabrication process.

3. Main advantages of the offer

Globally, the industrial application of the project will improve the existing therapeutic treatments.

The advantages expected by its industrial application are:

1. Fabrication procedure simple and economic;

2. Low environmental impact, since its preparation does not require the use of organic solvents;
3. Improved efficiency of drug delivery, since the film is thin and flexible and then it adapts perfectly the skin surface;
4. Reduction of skin irritation, since the film is water permeable;

The film can be used for iontophoretic application, a physical enhancing strategy to improve drug penetration across the skin.

4. Technology key words

Patch-non-Patch®, bioadhesive film, dermal/transdermal delivery.

5. Current Stage of Development

Work in progress – Tested in laboratory

6. Intellectual Property Rights

Two patent application named “Film for active ingredients dermal and transdermal administration” PCT WO 02/30402 A2 and “New device for delivery of active principles” WO2006008320, have been filed for this product. Licensing or transfer is available.

Technical and scientific publications

- Stratum corneum distribution of lidocaine in vivo from a new bioadhesive transdermal film, C. Padula, A. Fulgoni, P. Santi, *Skin Res. and Technol.*, 16, 125-130 (2010).
- Development and evaluation of occlusive systems employing polyvinyl alcohol for transdermal delivery of sumatriptan succinate, C. Balaguer-Fernández, C. Padula, A. Femenía-Font, V. Merino, P. Santi, A. López-Castellano, *Drug Delivery*, 17 (2), 83-91 (2010).
- Innovative formulations for the delivery of levothyroxine to the skin, C. Padula, S. Nicoli, P. Santi, *Int. J. Pharm.*, 372, 12-16 (2009).
- Physical characterization of a new skin bioadhesive film, A. Nussinovitch, A. Gal, C. Padula, P. Santi, *AAPS Pharm. Sci. Tech.*, 9 (2), 458-463 (2008).
- Transdermal Film Containing Nicotine and Bupropion for Combined Smoking Cessation Therapy, S. Nicoli, S. Cella, V. Aversa, P. Santi, *Pharmaceutical Technology Europe*, 20 (2), 22-29 (2008)
- Bioadhesive film for dermal and transdermal drug delivery, C. Padula, S. Nicoli, V. Aversa, P. Colombo, F. Falson, F. Pirot, P. Santi, *Eur. J. Dermatol.*, 17 (4), 309-312 (2007).
- Single-layer transdermal film containing lidocaine: modulation of drug release, C. Padula, S. Nicoli, P. Colombo, P. Santi, *Eur. J. Pharm. Biopharm.*, 66 (3), 422-428 (2007)
- Tecnologia Patch-non-Patch, S. Nicoli, P. Santi, *Kosmetika*, 8, 54-56 (2006).
- New transdermal bioadhesive film containing oxybutynin: in vitro permeation across rabbit ear skin, S. Nicoli, E. Penna, C. Padula, P. Colombo, P. Santi, *Int. J. Pharm.*, *Int. J. Pharm.*, 325, 2-7 (2006)
- Bioadhesive mono-layer film for the in vitro transdermal delivery of sumatriptan , A. Femenía-Font, C. Padula, F. Marra, C. Balaguer-Fernández, V. Merino, A. López-Castellano, S. Nicoli, P. Santi, *J. Pharm. Sci.*, 95(7), 1561-1569 (2006).
- Release and permeation kinetics of caffeine from bioadhesive transdermal films, S. Nicoli, P. Colombo, P. Santi, *The AAPS Journal*, 7 (1), art 20 (2005)
- Bioadhesive transdermal film containing caffeine, S. Nicoli, V. Amoretti, P. Colombo, P. Santi, *Skin Pharmacol. and Physiol.*, 17 (3), 119-123 (2004)
- Bioadhesive film for the transdermal delivery of lidocaine: in vitro and in vivo behavior, C. Padula, G. Colombo, S. Nicoli, P.L. Catellani, G. Massimo, P. Santi, *J. Control. Release*, 88 (2), 277-285 (2003)

CONTACT

info@biopharmanet.eu

Tel.: +39 0521 905073 Fax: +39 0521 905006