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Evaluation of the adhesion performance of different transdermal formulations by means of thermography in comparison with the classical visual approach as proposed by FDA

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New transdermal patch formulations have recently gained importance in therapy due to peculiar advantages in various aspects like increasing compliance, permitting stable long-term release and better PK profile in case of relevant first-pass effect. A critical issue related to the development of the transdermal patches is the evaluation of the adhesion properties, directly related to their PK performance. Thus, it is mandatory in the development of transdermal patches to include adhesion performance evaluations (FDA, EMA guidances). The classic method with visual approach and photographic documentation combined with the automatic reading of the data bring us to obtain good results, which however weren't fully satisfactory. The use of a new thermo-graphic camera capable to obtain surface temperature maps (considering that the surface temperature will locally decrease in areas with inadequate contact to skin) has been tested. The thermo mapping method is very fast and avoid any contact with the patches surfaces. The results obtained with this new thermo-graphic technique have been compared to the classic method and while many small adhesion alterations, most probably irrelevant in the absorption process are not appreciated, the areas where discontinuity skin-patch are present can be easily detected. Comparisons with PK data performed until now seem to support the validity of this new thermo-graphic method that will relevantly simplify and improve the transdermal patches adhesion evaluation, being in the same time more objective than the classical visual approach evaluation.

Biography

Simona Rizea Savu graduated in Medicine in Bucharest (Romania) in 1991 and obtained a Doctorate in Pharmacology in 2004. From 1992 to 2002 she was Researcher in Pharmacology at the ICCF institute of Bucharest; in 1994, during a Fellowship in Germany, has acquired expertise in HPLC-MS for bioanalytical applications. In 1996, she co-founded 3S-Pharmacological Consultation & Research GmbH, a German consultation company and CRO, focused on support, like clinical trials and analytical services, for pharmaceutical companies. In her scientific activity she has contributed to several articles in international scientific journals.

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