UDC 615.272.

TRANSDERMAL PATCHES

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Abstract: *Transdermal patches are one of the safest forms of drug delivery and, in some cases, the only way to administer the drug. However, for these innovative tools to provide the maximum effect, certain aspects of their safe and effective use should be considered.*

Key words: *transdermal patches, product, medicine, cellulose, skin.*

Аннотация: *Трансдермальные пластыри являются одной из самых безопасных форм доставки лекарств, а в некоторых случаях и единственным способом введения лекарства. Однако для того, чтобы эти инновационные средства давали максимальный эффект, следует учитывать некоторые аспекты их безопасного и эффективного использования.*

Ключевые слова: *трансдермальные пластыри, продукт, лекарство, клетчатка, кожа.*

Transdermal patches are flexible pharmaceutical preparations of various sizes containing one or more active ingredients. They are intended for application to unaffected skin in order to release the active substance or substances into the systemic circulation through the skin barrier.

Transdermal patches usually consist of an outer shell that holds the drug with the active ingredient or ingredients. Transdermal patches are coated at the site of release of the active substance with a protective layer, which is removed before applying the patch to the skin. The outer shell is an impervious to the active substance or substances and usually to water, a plate designed to contain and protect the medicinal product. The outer shell may have the same dimensions as the drug itself, or it may be larger in size. In the latter case, the protruding edge of the outer sheath is covered with pressure-sensitive adhesives that allow the patch to be applied

to the skin. The medicinal product contains the active substance or substances and excipients, such as stabilizers, solubilizers, or substances that change the release rate of the active substance or substances or increase transdermal absorption. This may be a single-layer or multi-layer solid or pasty matrix, in which case its composition and structure determine the diffusion of the active substance or substances on the skin. The matrix may contain pressure-applied adhesives that allow the drug to be applied to the skin.

The medicine may exist in the form of a semi-solid plate, one side of which is a shell that controls the release and diffusion of the active substance or substances from the drug. In this case, the pressure-sensitive adhesives may be located on individual sections of the sheath or on the entire sheath or only on the edge of the outer sheath. When applied to dry, clean and undamaged skin, the patch firmly adheres to the skin by light pressure with a hand or fingers and is removed without causing noticeable damage to the skin or displacement of the drug from the outer shell. The patch should not cause irritation or hypersensitivity of the skin even after repeated applications. The protective layer is usually made of plastic or foil. When it is removed, the drug or adhesive should not separate from the patch.

Transdermal patches are usually available in individual sachets. In the production, packaging, storage and sale of transdermal patches, measures are taken to ensure microbiological purity in accordance with the requirements of the article "Microbiological purity medicines".

Transdermal patches must pass the uniformity test for the content of the active substance in the dosage unit (test C), unless otherwise specified in the sub-article.

Conduct a test to confirm the appropriate release of the active substance or substances. Depending on the composition, size and shape of the patch, either the assembled disk method, or the cell method, or the rotating cylinder method is used. If a membrane made from materials such as inert porous cellulose or silicones is used, it should not interfere with the release kinetics of the active substance or substances from the patch. In addition, the membrane must be free of substances that may interfere with its action (eg. fat). The membrane may be suitably treated before

testing, for example by keeping it in the test environment for 24 hours. Apply the membrane to the protruding edge of the patch, avoiding the formation of air bubbles. The conditions for the test and the requirements for it should be specified in a private article.

This guideline addresses the general requirements for the development and quality of transdermal patches for their registration and modification of the dossier. In addition, specific recommendations are provided regarding data requirements to justify the registration of generic drugs (along the shortened path).

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