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QPS White Paper

Transdermal Delivery Systems

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Topical Transdermal Delivery Systems (TDDS) are designed to treat systemic medical conditions or localized joint or muscle conditions using the skin as the route of drug delivery. Whereas dermatologic topical formulations (foams, creams, lotions, ointments, gels, etc.) target skin diseases. Transdermal drug delivery offers important advantages over other routes of administration. It is particularly useful as an alternative to oral products, for circumventing liver first-pass metabolism, as an alternative to oral products, for non-invasive localized muscle and joint treatments, to improve and simplify patient compliance, and to allow for discontinuation of drug delivery by removing the patch in the event of adverse drug reactions. TDDS have become successful alternatives for delivering medications to young children, the elderly and the infirm.

TDDS Are Well Established

From the first transdermal patch for motion sickness (Scopolamine; Transderm Scop®; Novartis Consumer Health, Inc.) approved by the FDA in 1979, to the most recently approved patch, for chronic pain (Buprenorphine; Butrans®;PurduePharmaL.P.), a total of 22 transdermal systems have been commercialized as prescription products. In addition, several over-the-counter (OTC) products are also available, including patches containing nicotine, oxybutynin, capsaicin, and menthol, to name a few.

The Transdermal Delivery System Industry Is Growing, Worldwide.

Representing more than 12% of the global drug delivery trade, this market was valued at $5,400.2 million in 2017 and is projected to grow at a CAGR of 4.6%. Transdermal Patch market size is expected to maintain the average annual growth rate of 2.69% from $7,367 million in 2013 to $7,977 million in 2016. Market analyst believe that in the next few years, Transdermal Patch market size will be further expanded. We expect that by 2021, the market size of the Transdermal Patch will reach $9,388 million.

Pharmaceutical, biotechnology, and drug delivery companies continue to evaluate new applications for transdermal drug delivery including treatments for migraine, HIV, osteoporosis, stroke and restless leg syndrome. The future development of successful transdermal drug delivery systems in a widening array of therapeutic areas will play an important role in improving patients' quality of life by providing alternatives to conventional oral and injectable drugs.

Beyond The Proprietary Products, The Generic Industry Is Rapidly Expanding The Market With Bioequivalent Transdermal Systems.

The approval process for transdermal generic products has been facilitated by the FDA with recommendations outlining the necessary studies for demonstrating not only bioequivalence (systemic delivery), but also non-inferiority for adhesion, irritation and sensitization to the reference product, issued in 2010 [1]. The FDA has also recently issued a guidance related to residual drug content for transdermal systems, which was last updated in August 2011. [2]

Developing New Transdermal Systems

This presents challenges in identifying the best body site for application, establishing bioavailability, monitoring efficacy, determining the appropriate duration of application, and quantifying residual drug. Adhesion, irritation and sensitization must also be considered. A well designed and integrated development plan is needed to achieve rapid approval.

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Transdermal Drug Delivery Systems

Although transdermal systems are classified variously, transdermal patches can be divided into three main categories according to how the drug is incorporated into the delivery system:

- **An adhesive matrix** patch is a system in which the adhesive layer contains the drug. In this type of patch, the adhesive layer not only serves to fix the TDDS to the skin but is also responsible for the controlled release of the drug.
- **A reservoir** patch is a system with a liquid compartment containing a drug solution or suspension, enclosed by an adhesive layer and a semi-permeable membrane to control release.
- **A matrix** patch is a system which includes a semisolid matrix containing a drug solution or suspension, independent of the adhesive.

Non-patch topical transdermal systems have also become popular. They are typically gels and creams, such as those designed to deliver testosterone, progesterone, and diclofenac sodium.

Apart from traditional transdermal patch products, extensive work is ongoing to develop microporation technologies and devices, most of which are intended to disrupt or bypass the stratum corneum, the rate-limiting barrier of the skin. Microporation techniques currently in development include laser ablation, radiofrequency (iontophoresis, sonophoresis, electroporation), thermal technologies (drug delivery augmented with heat), and microneedle systems. These diverse developing technologies are being investigated for use with a wide variety of difficult-to-deliver drug compounds and macro- molecules (e.g. parathyroid hormone, insulin, vaccines, and biologics), and for drugs requiring rapid delivery (e.g. lidocaine, fentanyl and diclofenac)

Several of these systems are already available OTC, including microneedle rollers and iontophoresis and sonophoresis systems, which are predominately being used for cosmetic and anti-aging treatments and as therapy for localized sports injuries.

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QPS Knows Transdermal Product Development

QPS possesses extensive study conduct experience and familiarity with the relevant regulatory guidances, to support your transdermal product development in both the NDA and ANDA arenas. We understand the complexities, especially with regard to preclinical and clinical bioavailability, proof of concept, bioequivalence, and skin irritation and skin sensitization studies. We look forward to helping you explore the use of new drug delivery patch systems, novel permeation enhancement techniques for macromolecules, generics, and other conventional molecules for a wider range of indications. Our staff is committed to working with you to advance your transdermal product portfolio in this rapidly developing market segment, for the benefit of patients worldwide.

Broad Access

At QPS, we offer clients broad strategic access to our extensive transdermal experience collected across diverse therapeutic areas and special populations. Our preferred vendor agreements also provide for the establishment of client- dedicated units within our organization.

Timely Delivery

Partnering with QPS will position you to succeed in the timely delivery of your transdermal products to the marketplace.

References

[1] Bioequivalence Recommendations for Specific Products [https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development]

[2] Residual Drug in Transdermal and Related Drug Delivery Systems [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/residual-drug-transdermal-and-related-drug-delivery-systems]