

Transdermal Drug Delivery - Clinical and Regulatory Strategies

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Transdermal delivery of a drug product which is currently approved as oral dosage form, allows for the avoidance of first pass metabolism by the liver and the delivery of a more even level of the therapeutic agent over the course of 24 hours. Dermal patches are the most common form of transdermal delivery of drugs. To obtain FDA approval of a transdermally delivered drug, it is critical to involve the Food and Drug Administration (FDA) early in the development process. A strategy should be implemented to involve as much pharmacokinetic data as possible to demonstrate similar area under the curve but different maximum concentration and time to maximum concentration. To support the Investigational New Drug Application (IND), standard irritation and sensitization studies should be performed with the patch itself in animals, and if feasible, normal volunteers. There will be toxicology requirements, but the extent and timing of their implementation can be negotiated with the FDA. The dermatology division at FDA will review dermal aspects of the IND and New Drug Application (NDA), but the primary review will occur at the division which handles the indication under study. Dose ranging studies will usually be required in Phase 2, but a single Phase 3 study could be negotiated.

Key Words: Transdermal Drug Delivery, Dermatology, Skin, Pharmacokinetics