A transdermal drug delivery system (TDDS) or transdermal patch is a flexible pharmaceutical preparation of different size containing one or more active substance(s) to be applied on the intact skin for systemic availability. A generic TDDS is defined by having the same amount of active substance released per unit time as compared to the reference TDDS.

It is notable that this definition is different from the general definition of a generic since the overall amount of active substance could differ while the labelled amount of active substance remains the same. Therefore, compared to other generic developments, the required studies for developing a generic TDDS are more complex and differences between region-specific requirements are more pronounced.

The objective of this presentation is to discuss the differences and similarities between the requirements requested by FDA and EMA for developing a generic TDDS.

Both FDA and EMA guidance were reviewed.

TDDS products included Mexiletine, Estradiol, Nicotinone, Fentanyl, Clonidine, Ethinyl Estradiol, Roflumilast, Buprenorphine, Nitroglycerine, Rosiglitazone, Selegiline, and Revastigmine were reviewed.

For the above products, the FDA has issued product-specific guidelines for each particular patch whereas the EMA defines the requirements in general guidelines for "modified release products" and their relevance to each patch requires to be followed up with the agency in each individual case.

FDA general guidance for Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs [2] was compared with the EMA Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms [1].

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