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TITLE

BIOEQUIVALENCE IN TRANSDERMALS

Charu Gautam

Director- Clinical Operations,
BA Research India Ltd.,
Ahmedabad, India.

Transdermal drug delivery system has been in existence for a long time. In the past, the most commonly applied systems were topically applied creams and ointments for dermatological disorders. Now there are novel patches in various therapeutic areas. The Transdermal Drug Delivery System (TDDS) offers several advantages over the traditional orals and injectables. It is a controlled release of drug, does not require frequent dose, is painless and most importantly does not undergo first pass metabolism.

With such advantages, the Pharmaceutical industry is developing several TDDS for drugs used in elderly, children, chronic illness etc.

Bioavalability with transdermals poses certain challenges such as variability, physicological differences and formulation differences.

The patches also pose problems such as skin sensitization and irritability. One of the important aspect is adhesivity of the patch. Considering the various factors affecting the bioavailability of transdermals, the regualtory has defined certain guidelines for the conduct of such studies.

The bioequivalence of a TDDS in comparison to the innovator's product should usually be assessed after single dose as well as after multiple dose administration;

- The site of application for the bioequivalence study should be in the same body area for both test and reference product;
- As patches are often highly variable drug products it is recommended to assess the intra-individual variability and, in particular, to determine the influence of biopharmaceutical performance on this variability by conducting a study with replicate design;
- If TDDS with different release mechanism (reservoir versus matrix) are compared a study using replicate design is required to investigate subject by formulation interaction;
- both products should demonstrate the same or less degree of local irritation, adhesiveness to the skin, phototoxicity (phototoxic potential), sensitization and similar systemic adverse events profile compared to the reference product;
- Bioequivalence is assessed using the same main characteristics and statistical procedures as for the prolonged release formulations.

Reference: CPMP/EWP/280/96 ©EMEA 1999 8/11