VEEDA'S EXPERTISE IN HANDLING TRANSDERMAL PATCH CLINICAL STUDIES

INTRODUCTION :

A **transdermal** patch is a medicated adhesive patch that is placed on the skin to **deliver** a specific dose of medication through the skin and into the bloodstream.

As the layers of skin absorb medication from **transdermal patches** (trans meaning through and dermal referring to the dermis (skin)), the medication is absorbed via the blood vessels into the bloodstream. From there, the blood carries medication through the circulatory system and through a patient's body.

Different types of study for Transdermal Patch :

1. Bioequivalence (BE) with Pharmacokinetic (PK) Endpoints Study

Adequate skin contact is essential for the in vivo performance of the transdermal patch. Therefore the adhesion of each transdermal patch should be monitored and recorded throughout the PK study. Overlays should not be used during the study.

2. Adhesion Study

The recommended scoring system for adhesion of transdermal patches is indicated as follows :

- *0 = ≥ 90% adhered (essentially no lift off the skin)*
- *1 = ≥ 75% to < 90% adhered (some lifting off the skin e.g., edges only)*
- *2 = ≥ 50% to < 75% adhered (less than half of the patch lifting off the skin)*
- *3 = > 0% to < 50% adhered but not detached (more than half of the patch lifting off the skin without falling off)*
- *4 = 0% adhered - patch detached (patch completely off the skin)*

3. Skin Irritation and Sensitization Study

Adequate skin contact is essential for maximal induction of irritation and sensitization and it may be altered when a patch loses its adherence to the skin. Therefore, the adhesion of each patch should be monitored and recorded throughout the irritation and sensitization study

The same anatomical site should be used for the entire study.

Subjects should not apply make-up, creams, lotions, powders, or other topical products to the skin area where the patch will be placed, as this could affect adhesive performance or irritation potential.

CHALLENGES :

To get Compliance from subject for adhesion during study Experienced and trained staff for applying patch on specific site.

VEEDA'S STRENGTH AND CAPABILITIES IN PATCH STUDY :

- Total 5 patch study (4 Pivotal, 1 Pilot) with total no. of 206 volunteers has been done in Veeda and some are in pipeline.
- Good number of **healthy volunteers data base including postmenopausal women** who have participated previously in patch study and having good compliance as per protocol requirement
- We have done the **housing** of subjects up to 120 hour post dose with patch applied with good compliance from subject
- Well **trained and experienced staff** for applying patch on the predefined site as per protocol
- Well **experienced Investigator** who are having in depth knowledge of patch study as per regulatory guideline
- We are having **ACLS and BLS trained clinical staff** for handling any serious adverse event
- **No any serious adverse event** reported in patch study

Veeda Advantage

- 100% data review by Bio-analytical Quality Monitors
- State of art Bio analytical Lab equipped with highend sensitive equipment's to achieve the required LLOQ.
- Trained Bio analysts to handle complex sample processing
- Proven regulatory track record with 11 USFDA, 5 European, 4 WHO & 5 ANVISA audits
- Bio-analytical Unit with more than 590 validated assays in its library of compounds including 36 NCE methods, 20 more under development.

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