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Short Communication
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Vasoconstrictor Assay Method for the Bioequivalence Assessment of Topical Corticosteroid Applications: A Complex and Variable Approach

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Skin blanching due to topical corticosteroids was initially observed by [1,2] introduced the assessment of bioequivalence (BE) of topical corticosteroids using Vasoconstrictor Assay (VCA)/ Skin Blanching Studies. Eventually, based on these findings, US-FDA issued interim guidance in 1992 and final guidance in 1995 on "Topical Dermatological Glucocorticoids: In vivo Bioequivalence" [3]. From 1995, these guidelines were adapted and recommended by all major regulatory authorities for the BE assessment of topical corticosteroids. In principle, this method relies on the unique ability of topical corticosteroids to produce a blanching response as a result of vasoconstriction of the skin microvasculature. The basis of this approach is the measurement of the pharmacodynamic

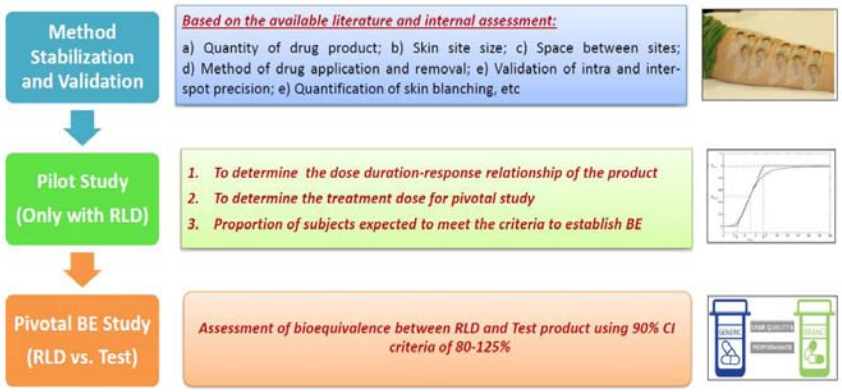

Figure 1: Main steps involved in the assessment of bioequivalence of topical corticosteroids using Vasoconstrictor Assay.

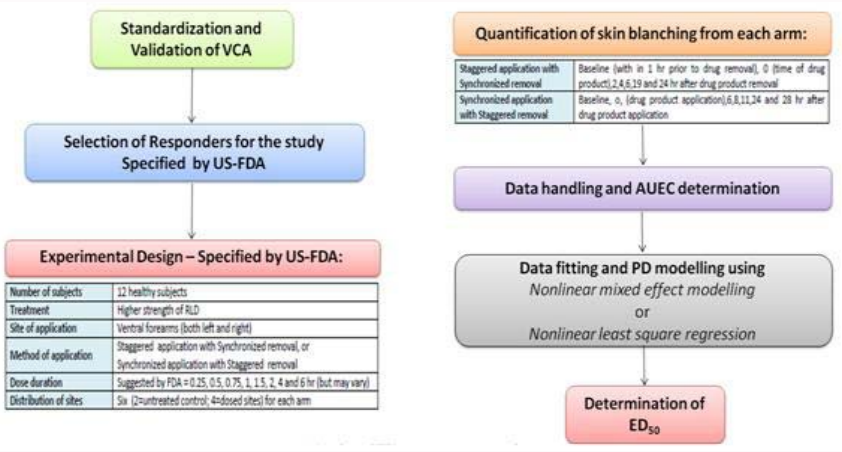

Figure 2: Main steps involved in the pilot study of Vasoconstrictor Assay VCA=Vasoconstriction Assay, US-FDA=United States Food Drugs Administration; AUEC = Area Under the Effective Curve, PD = Pharmacodynamic; ED_{50} = Dose Duration at which Effect is Half-maximal.

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