F. No. 12-09/2019/BA-BE/Misc-53/DC
Government of India
Directorate General of Health Service
Central Drugs Standard Control Organisation
(BA/BE Division For Export)

FDA Bhawan, New Delhi
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CIRCULAR

Subject: Clarification on stability data requirement in case of Clinical Trial and Bioavailability - Bioequivalence (BA-BE) study-reg.

The concerns have been raised at various forums with respect to the requirement of stability study data to be submitted along with application for grant of permission to conduct Clinical Trial and BA-BE studies.

In this regard, it is to clarify that, as per the rule position with respect to Clinical Trial, stability studies data is required to be submitted as per Table 1 of Second Schedule of New Drugs and Clinical Trials Rules, 2019, wherein it is mentioned that;

> "When the application is for clinical trials only, the international non-proprietary name (INN) or generic name, drug category, dosage form and data supporting stability in the intended container-closure system for the duration of the clinical trial are required".

The definition of Clinical Trial as per New Drugs and Clinical Trials Rules, 2019 is as follows;

> "Clinical trial" in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,-
> (i) clinical or;
> (ii) pharmacological including pharmacodynamics, pharmacokinetics, or;
> (iii) adverse effects,
> with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug.

The comparative pharmacokinetic studies are generally conducted in the form of bioequivalence studies which is defined in the Rules as under:

> "Bioequivalence study" means a study to establish the absence of a statistically significant difference in the rate and extent of absorption of an active ingredient from a pharmaceutical formulation in comparison to the reference formulation having the same active ingredient when administered in the same molar dose under similar conditions.

Further, it is also clarified in the Note 1 of Table 2 of Fourth Schedule that all items may not be applicable to all drugs and for explanation, text of First Schedule, Second Schedule and Third Schedule shall be referred.

This is for further guidance and clarification in this regard as per the requirements of the New Drugs and Clinical Trials Rules, 2019.

V.G.

(Dr. V.G Somani)
Drugs Controller General (India)

To: All Stakeholders through CDSCO websites