F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/12/2020

NOTICE

Subject: Stability data for BA/BE study in human for export- reg.

CDSCO receives and process application for permission to conduct BA/BE study in human for export.

Concerns have been raised that 3 month accelerated and long term stability data are required during submission of such application.

In this regard, it is clarified that as per the provisions of the Second Schedule of the New Drugs and Clinical Trials Rules, 2019 when the application is for clinical trials only, the stability data supporting the stability of the investigational new product in the in the intended container-closure system for the duration of the clinical trial are required.

However, depending on the product development one month stability data may be accepted for issuance of the BE NOC for export. While conducting the BE study, the firm shall submit the updated stability data to ensure the stability of the product throughout the BE study.

Yours faithfully,

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

To,

1. **All Stakeholders.**