

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: 21/2/2020

**NOTICE**

**Subject: Permission to conduct BA/BE study and clinical trial – reg.**

Under the provision of New Drugs and Clinical Trials Rules 2019, CDSCO receives applications for grant of permission to conduct clinical trial/BA-BE study as part of requirements for grant of permission to manufacture or import of new drugs.

Concerns have been raised and changes have been proposed for processing and approval of such applications for conduct of clinical trial/BA-BE permission simultaneously.

In this regard, it is to mention that, in general, such applications are processed in accordance with the New Drugs and Clinical Trials Rules, 2019, and if found satisfactory, permission to conduct BA/BE study and clinical trial are granted simultaneously, subject to condition that CT should be conducted after submission of BA/BE study result.

Yours faithfully,



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

To,

1. All Stakeholders.