

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: Fixing of limit of impurities in the specification of INDs – reg.

CDSCO receives and process application for clinical trial of Investigational New Drugs (INDs) in accordance with the provisions of New Drugs and Clinical Trials Rules 2019.

Concerns have been raised regarding the fixing of limits of impurities in the specifications of such INDs.

In this regard, it is clarified that IP prescribes the general limits for impurities in the specifications. However, the applicant when submit scientific justifications in support of limits of impurities beyond that specified in IP, the same are considered and accepted.

Yours faithfully,



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

To,

1. All Stakeholders.