

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: 13/3/2020

NOTICE

Subject: Testing of all categories of new drugs for their approval – reg.

Under the New Drugs and Clinical Trials Rules, 2019, CDSCO grants permission for import/manufacture of new drugs for sale and distribution. One of the requirements is testing of the new drugs in the Central Government Laboratories before their approval.

Concerns have been raised regarding requirement of such laboratory testing of new drugs which are pharmacopoeial products or which are additional strengths of already approved new drug.

In this regard, to streamline the new drug approval process, it has been decided that, testing will be carried out by the Central Government Laboratories as per the following timelines unless otherwise, there is any specific issue involved relating to testing of the drug.

Categories of new drug	Timeline
New drugs already approved	4 weeks
New drugs which are pharmacopoeial	6 weeks
Other new drugs	8 weeks

Yours faithfully,


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

To,

1. All Government Laboratories.
2. All Stakeholders.