

F.No.PG/298/import/TL/2019-DCGI  
Government of India  
Directorate General of Health Services.  
Central Drugs Standard Control Organization  
(Public Grievance Cell)

FDA Bhawan, Kotla Road  
New Delhi-110002,

Dated 20/2/2020

To,  
All State/UT Drugs Controller,

**Subject: Grant of License in Form 29 under the Drugs and Cosmetics Rules, 1945 - reg.**

Sir / Madam,

Under the provision of Drugs and Cosmetics Rules, 1945, State Licensing Authorities grant licenses in Form 29 to manufacture drugs for purpose of examination, test or analysis, CT or BA/BE study.

However, under the New Drugs and Clinical Trials Rules, 2019, the applicant is required to obtain permission from CDSCO for new drugs and Investigational New Drugs, before obtaining the license in Form 29 under the Drugs and Cosmetics Rules, 1945.

Concerns have been raised on certain aspects of submission and processing of such applications under the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Rules, 1945.

In this regard, recently, CDSCO has issued a Notice No. 12-01/20-DC (Pt. 51) 18.02.2020 giving clarity on various aspects relating to submission and processing of such applications for grant of permission to manufacture trial batches of new drug or investigational new drug for test and analysis, CT or BA/BE study.

Further, to streamline the process, CDSCO has also decided that such applications under New Drugs and Clinical Trials Rules, 2019, will be processed within 07 working days and accordingly, a Notice has been issued vide No.PG/298/import/TL/2019-DCGI dated 20.02.2020.

Copies of the above mentioned two Notices are enclosed for ready reference.

In view of above, you are requested to consider that applications for grant of license in Form 29 under the Drugs and Cosmetics Rules, 1945 are also processed within 07 working days of receipt of the applications.

Yours faithfully,

*V.G.S.*

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

Copy for information to:-  
JS(R), MoHFW, Nirman Bhavan, New Delhi