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: 13/3/2020

NOTICE

Subject: Requirement of process validation report for permission to conduct Clinical trial/BA-BE studies – reg.

Under the New Drugs and Clinical Trials Rules, 2019, CDSCO grants permission for import/manufacture of new drugs for sale and distribution.

Concerns have been raised regarding requirement of process validation report for permission to conduct clinical trial/BA-BE studies.

In this regard, it is mentioned that data to be submitted along with the application to conduct clinical trials or import or manufacture of new drugs (new molecule) for sale in the country are specified in Table 1 of Second Schedule of New Drugs and Clinical Trials Rules, 2019.

As per the said table when the application is for clinical trials only, the international non-proprietary name (INN) or generic name, drug category, dosage form and data supporting stability in the intended container-closure system for the duration of the clinical trial (information covered in item numbers 2.1, 2.3, 2.6, 2.7 of the table) are required.

Process validation as required for commercial batches may not be required for Phase I, Phase II studies, However, the proof of process standardization may be required . Further, for the phase III clinical trial batches the requirements of process validation though may not be required as per commercial batches , however, it will vary depending on the complexity of the product (biological, high tech etc)

Yours faithfully,

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

To,

All Stakeholders.