F. No. 12-44/2019-DC (Pt- Misc)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan, New Delhi
Dated: 30/01/2019

CIRCULAR

Subject: Clarification on manufacturing of new drug by a manufacturer in their own multiple manufacturing sites - reg.

Requirements for manufacturing of new drug by a manufacturer in its own additional site has been under discussion for quite some times now.

For generation of Chemistry, Manufacturing and Control (CMC) data, the manufacturer needs to obtain license/permission from concerned Authority.

The matter has been examined and it has been decided that if CMC data is generated by a manufacturer in one of its manufacturing facility and based on the data the approval/permission has been granted to the manufacturer for manufacturing of the new drug in that facility, the same data may be utilized by the same manufacturer for manufacturing of same product in its additional manufacturing sites with necessary permission/license provided that the manufacturer establishes the similarity by way of technology transfer with respect to manufacturing process, equipment, process parameters, process capability and bridging validation for technology transfer wherever required etc. between the proposed additional manufacturing sites and the approved manufacturing site.

V.G.S.

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

To: All Stakeholders through CDSCO website