

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: 2-11-2020

NOTICE

Subject: Requirement of Stability Data for COPP – reg.

Certificate of Pharmaceutical Product (COPP) is issued under the WHO GMP Certification Scheme for the purpose of international commerce i.e. for registration of products in foreign countries.

Concerns have been raised regarding requirement of stability data on the commercial batches before grant of WHO GMP and COPP.

In this regard, it is clarified that if the stability data is generated during development stage as per the WHO guidelines, no further stability data on the commercial batches are required before grant of WHO GMP and COPP.

Yours faithfully,



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

To,

1. All Stakeholders.