

7-5/2020/Misc/070
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110002.

Dated:- 1/5/2020

To,
All States/UT Drugs Controllers

Subject: Extension of validity of WHO GMP/Certificate of Pharmaceutical Product (COPP) -
Regarding

Sir/Madam

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. Earlier the validity of CoPP was extended from 2 years to 3 years vide Office Memorandum No. 7-5/2018/Misc/048 dated 08.05.2018.

This office has received representations from stakeholders requesting to extend validity of WHO GMP Certificate/CoPP whose validities are expiring between now and August 2020 in view of COVID-19 outbreak.

The matter has been examined in light of current situation of COVID 19 outbreak and in order to maintain the continuity of essential activities by the pharmaceutical industry, it has been decided that validity of WHO GMP/CoPP expiring from March to August 2020 may be extended by 6 months from the date of expiry of the certificate as per WHO GMP Certification guidelines..

Yours Faithfully,

V. G. Somani

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

Copy to:

- 1- PS to JS (R), MoHWF, GOI, Nirman Bhawan, New Delhi
- 2- All Zonal, Sub-Zonal offices of CDSCO