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Directorate General of Health Services
Central Drugs Standard Control Organisation
O/o Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi - 110002
Dated: 08 MAY 2018

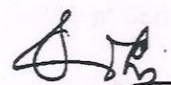
Office Memorandum

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.

This office has received representations from the stakeholders for extending the duration of the validity of the Certificate from 2 years to 3 years.

The matter has been examined by CDSCO in consultation with WHO (HQ), Geneva and the Ministry of Health & Family Welfare, Government of India and it has been decided that it should be considered as per the WHO Guidelines.

Accordingly, it has been decided that henceforth, the Certificate of Pharmaceutical Product (COPP) should be issued under the WHO GMP Certification Scheme with duration of validity of 3 years subject to condition that the GMP status of the manufacturing facility should be monitored as per WHO guidelines through inspection on a periodic interval.



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

To:

1. All States/UTs Drugs Controllers.
2. All Zonal, Sub-Zonal offices of CDSCO.

Copy for information to:

1. Joint Secretary (R), MOHFW, GOI, Nirman Bhawan, New Delhi.
2. Joint Secretary (Pharma), Ministry of Commerce and Industry, GOI
3. DG, Pharmexcil,
4. Members of Indian Drugs/Pharmaceuticals Association Forum
5. OPPI
6. WHO Representative to India, New Delhi