सत्यमेव जयते

CDSCO IT-13011(12)/7/2025
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan. Kotla Road,
New Delhi-110002

Dated: 26.09.2025

To
All State/UTs Drugs Controllers

Subject: **Processing of Grant of WHO GMP COPP applications in respect of products under consideration for license approval through ONDLS Portal -reg.**

Sir/Madam,

It has been decided that applicants may now submit applications for issuance of COPP/WHO-GMP certificate even for products where the product license is under consideration with the concerned State Licensing Authority.

In such cases, the applicant shall first submit the complete license application along with all requisite data to the State Licensing Authority for approval. During the period in which the product license application is under examination, the applicant may simultaneously apply for COPP/WHO-GMP for the said product.

However, it is to be noted that before grant of COPP/WHO-GMP, the concerned State Licensing Authority must ensure that the product license has been duly approved, and that the old license data, wherever applicable, has been verified and accepted.

Therefore, the processing of COPP/WHO-GMP applications shall be done in parallel with product license applications, but the final approval and issuance of COPP/WHO-GMP shall be made only after confirmation of product license approval by the State Licensing Authority.

All State Licensing Authorities are requested to take note of the above and ensure strict compliance.

Yours faithfully

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:

1. **All Zonal and sub zonal office of CDSCO with direction ensure strict compliance.**
2. **All Pharmaceutical associations.**