CERTIFICATE OF PHARMACEUTICAL PRODUCT (COPP)

PREPARED BY:

MR. SANKET S. VYAS

ASSOCIATE PROFESSOR

M.PHARM

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COPP/CPP

* The **certificate of pharmaceutical product** is a certificate issued in the format recommended by the World Health Organization (WHO), which establishes the status of the pharmaceutical product.
* The CPP supports the review in countries without sufficient capability to conduct a full review themselves. Ideally, a CPP should not be required in countries that have the capabilities to conduct full reviews.

Importance

* The CPP should be used when a pharmaceutical product is under consideration for a product licence/marketing authorisation or when administrative action is required to renew, extend or vary such a licence.
* In the presence of such CPP, WHO recommends to national authorities to ensure that analytical methods can be confirmed by the national laboratory, to review and if necessary to adapt product information as per local labelling requirements, and to assess bioequivalence and stability data if necessary

* Certification has been recommended by WHO to help undersized drug regulatory authorities or drug regulatory authorities without proper Quality assurance facilities in importing countries to assess the quality of pharmaceutical products as prerequisite of registration or importation

COPP Application

* The application for grant of WHO GMP Certificate of Pharmaceutical Product shall be made to respective zonal/sub zonal officers as per the requirement.
* The COPP will be issued by zonal/sub zonal officers on behalf of Drugs Controller General (India) after inspection and satisfactory clearance by CDSCO officers as per WHO – GMP guidelines.

General requirements for submission of application for issue of COPP

* A forwarding application shall be addressed to DDC(I)/ADC(I) of respective CDSCO zonal/sub zonal offices with copy of covering letter & product summary sheet to DCF(I) by authorized person only.
* Application should clearly indicate for fresh certification(Grant) or reissue of products applied, accordingly it will be scrutinized for the products applied.

General requirements for submission of application for issue of COPP

* Applications will be reviewed by CDSCO officers and completed applications in all respects would be accepted for inspection on first come first serve basis
* The forwarding letter/application shall be accompanied with List of products applied for grant of COPP, along with the a product permission copy (manufacturing licence issued by the SLA) & notarized product summary sheet, site master file as per WHO-GMP requirement

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* List of major/master documents like master validation plan, quality manuals/ master formula records maintained y firm and list of SOP's
* Manufacturing layout
* List of personnel (with qualification and designation)
* List of euqipments,instruments

Procedure for accepting the application for issue of COPP

* All applications received will be scrutinized by CDSCO Officials after receipt and query letter will be sent to applicant, if any or otherwise will be considered for inspection.
* Inspection will be carried out by CDSCO Officers as per WHO GMP guidelines of TRS 823/908 for non sterile products, TRS 822/902 for Sterile Products and other relevant guidelines in TRS937, TRS 929, TRS 863 etc. as applicable from time to time.

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* Self appraisal checklist should be filled and submitted to CDSCO officer before inspection.
* Inspection team verify the checklist at the time of inspection.
* Inspectors brief the inspection findings at the exit meeting
* The report should clearly define deficiencies as per WHO GMP guidelines.

Contd.

* Respective Zonal/ Sub-Zonal certifying authority prepare "Review Report" based on review of observations of check list and written inspection report as per WHO GMP guidelines.
* Firm may reapply, if required after proper compliance after 5 months from date of rejection.

Format

* This certificate conforms to the format recommended by the World Health Organization.
  - No. of certificate
  - Exporting (certifying country)
  - Importing (requesting country)

1. Name and dosage form of the product:

1.1. Active ingredient(s) and amount(s) per unit dose

1.2. Is this product licensed to be placed on the market for use in the exporting country?(yes/no)

1.3 Is this product actually on the market in the exporting country?

If the answer to 1.2. is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B:[13]

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2.A.1. Number of product licence and date of issue

2.A.2. Product licence holder (name and address)

2.A.3. Status of product licence holder:

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is:

2.A.4. Is a summary basis for approval appended? (yes/no)

2.A.5. Is the attached, officially approved product information complete and consonant with the licence?11 (yes/no/not provided)

2.A.6. Applicant for certificate, if different from licence holder (name and address):

Contd.

2.B.1. Applicant for certificate (name and address):

2.B.2. Status of applicant:

2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)

2.B.4. Remarks:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable)

If not or not applicable, proceed to question 4

3.1. Periodicity of routine inspections (years)

3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?(yes/no/not applicable)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product: (yes/no) If no, explain:

Which countries require COPPs and why?

* Countries within regions, for example:
  - Latin America eg Panama , maxico,Agrentinia,peru ect
  - Asia Pacific Eg. Cambodia,chile, Bangladesh
  - Middle East/Africa eg. Egypt, Iran, Iraq, Israel,kuwait,Moracco etc
  - Eastern Europe / Commonwealth of Independent States (CIS). Eg.Belarus,Ukrain etc
* The COPP may be required to support a regulatory submission. This can be submitted at the beginning of, or during the health authority review.
* According to the WHO Scheme, COPPs should not be required in countries that require full ICH CTD dossiers and have the capability to conduct full QSE review.
* This certificate is valid for only 2 years fro date of issue.

References

1) https://en.wikipedia.org/wiki/Certificate_of_pharmaceutical_product
2) https://www.fda.gov/media/91749/download
3) https://www.slideshare.net/surajpamadi/copp-certificate-of
4) https://pharmafranchisehelp.com/certificate-of-pharmaceutical-products-copps/

THANK YOU...