

Annex 5

Model certificate of Good Manufacturing Practices

A model certificate of Good Manufacturing Practices (GMP) for a manufacturing site is suggested (see below). This is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce but is intended to serve in situations where a specific GMP certificate is requested by importers, exporters, procurement agencies and regulatory authorities. It is suggested that the certificate should remain valid for a period of 2 years from the date of issue, but not exceeding 3 years after the inspection was carried out.

It is recommended that, where possible, GMP certificates should have, e.g. security seals, watermarks or holograms, to help prevent counterfeiting, tampering and other fraudulent activities.

Letterhead of regulatory authority

Model Certificate of Good Manufacturing Practices

This one-page certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).¹

Certificate No: _____

On the basis of the inspection carried out on ____ [date] ____ we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name and address of site:

2. Manufacturer's licence number:

3. Table 1:

Dosage form(s)	Category(ies)	Activity(ies)

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until ____ [date] ____ It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority:

Name and function of responsible person:

Email: _____ Telephone no.: _____ Fax no.: _____

Signature:

Stamp and date:

¹ This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

Explanatory notes

- (1) This certificate, which is in the format recommended by WHO, certifies the status of the Site listed in point 1 of the certificate.
- (2) The certification number should be traceable within the regulatory authority issuing the certificate.
- (3) Where the regulatory authority issues a licence for the site this number should be specified. Record “not applicable” in case where there is no legal framework for the issuing of a licence.
- (4) Table 1

List the dosage forms, starting materials, categories and activities. Examples give below.

Example 1

<i>Pharmaceutical Product(s)</i> ²	<i>Category(ies)</i>	<i>Activity(ies)</i>
<i>Dosage form(s):</i>		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
	Penicillin	Repackaging and labelling
Injectables	Cefalosporin	Aseptic preparation, packaging, labelling

Example 2

<i>Pharmaceutical Product(s)</i> ²	<i>Category(ies)</i>	<i>Activity(ies)</i>
<i>Starting material(s):</i> ³		
Paracetamol	Analgesic	Synthesis, purification, packing, labelling

² Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

³ Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

Use, whenever available, International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

(5) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

(6) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in *Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2*, 1999. World Health Organization, Geneva and subsequent updates.