

**MEDICINES ACT
(CHAPTER 176, SECTION 74)**

**MEDICINES (GOOD MANUFACTURING
PRACTICE CERTIFICATE)
REGULATIONS**

ARRANGEMENT OF REGULATIONS

Regulation

1. Citation
 2. Definitions
 3. Application for GMP Certificate
 4. Fees
-

[1st June 2002]

Citation

1. These Regulations may be cited as the Medicines (Good Manufacturing Practice Certificate) Regulations.

Definitions

2. In these Regulations, unless the context otherwise requires —

“active pharmaceutical ingredient” means any raw material which is used as an active ingredient in the manufacture of a medicinal product;

“Good Manufacturing Practice Certificate” or “GMP Certificate” means a certificate relating to the manufacture of any medicinal product or active pharmaceutical ingredient attesting to its conformity with a Good Manufacturing Practice Standard;

“Good Manufacturing Practice Standard” means the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Co-Operation Scheme Guide to Good Manufacturing Practice for medicinal products or active pharmaceutical ingredients (as the case may be) or such other good manufacturing practice standard approved by the licensing authority.

Application for GMP Certificate

3.—(1) For the purposes of section 22 of the Act, an application for a GMP Certificate shall be made to the licensing authority in such form and manner as the licensing authority may require.

(2) Upon receipt of an application under paragraph (1), the licensing authority may, upon assessment of satisfactory conformity with a Good Manufacturing Practice Standard, issue a GMP Certificate to the manufacturer of any medicinal product or active pharmaceutical ingredient, subject to such terms and conditions as the licensing authority thinks fit.

(3) Every GMP Certificate issued under paragraph (2) shall be valid for a period not exceeding 2 years from the date of the certificate.

Fees

4.—(1) The fees payable for a GMP Certificate shall be as follows:

- (a) on application for a GMP Certificate — \$4,000; and
- (b) for each additional GMP Certificate — \$200.
which does not require further assessment
of conformity with any Good Manufacturing Practice Standard

(2) No refund shall be made in respect of any fee paid under paragraph (1).

[G.N. No. S 130/2002]
