MEDICINES ACT
(CHAPTER 176, SECTION 74)

MEDICINES (GOOD MANUFACTURING PRACTICE CERTIFICATE) REGULATIONS

ARRANGEMENT OF REGULATIONS

[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 —

(*a*) if issued before 1st February 2013, for a period not exceeding 2 years from the date of the certificate; and

(*b*) if issued on or after that date, for a period not exceeding 3 years from the date the assessment referred to in that paragraph is completed.

[S 37/2013 wef 01/02/2013]

Fees

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

(*a*) on application for a GMP Certificate	—	$6,570; and
(*b*) for each additional GMP Certificate which does not require further assessment of conformity with any Good Manufacturing Practice Standard	—	$220.

[S 491/2024 wef 01/07/2024]

[S 460/2022 wef 01/07/2022]

[S 99/2019 wef 02/04/2019]

[S 30/2007 wef 01/02/2007]

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

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

LEGISLATIVE HISTORY

MEDICINES (GOOD MANUFACTURING PRACTICE CERTIFICATE) REGULATIONS (CHAPTER 176, RG 16)

This Legislative History is provided for the convenience of users of the Medicines (Good Manufacturing Practice Certificate) Regulations. It is not part of these Regulations.

1. **G. N. No. S 130/2002 — Medicines (Goods Manufacturing Practice Certificate) Regulations 2002**

   Date of commencement : 1 June 2002

2. **2004 Revised Edition — Medicines (Good Manufacturing Practice Certificate) Regulations**

   Date of operation : 29 February 2004

3. **G. N. No. S 30/2007 — Medicines (Good Manufacturing Practice Certificate) (Amendment) Regulations 2007**

   Date of commencement : 1 February 2007

4. **G.N. No. S 37/2013 — Medicines (Good Manufacturing Practice Certificate) (Amendment) Regulations 2013**

   Date of commencement : 1 February 2013

5. **G.N. No. S 99/2019 — Medicines (Good Manufacturing Practice Certificate) (Amendment) Regulations 2019**

   Date of commencement : 2 April 2019

6. **G.N. No. S 460/2022 — Medicines (Good Manufacturing Practice Certificate) (Amendment) Regulations 2022**

   Date of commencement : 1 July 2022

7. **G.N. No. S 491/2024 — Medicines (Good Manufacturing Practice Certificate) (Amendment) Regulations 2024**

   Date of commencement : 1 July 2024