表題－1

Food and Drug Administration

Ministry of Public Health, Thailand

CERTIFICATE OF GMP COMPLIANCE

Ref. No.

It is hereby certified that:

Location at

is a manufacturer where has been inspected under the national inspection programme in connection with manufacturing licence no. in accordance with the Thai Good Manufacturing Practice requirements laid down in accordance with the recommendation of the Pharmaceutical Inspection Co-operation Scheme (PIC/S):

Certificate No. :
Date of Issue :
Valid Until :

(Dr. Suteep Bussayamanont)
Head of Post Marketing Control Division
For Secretary-General
Food and Drug Administration

Date .....

Bureau of Drug Control, Food and Drug Administration, Ministry of Public Health
88/24 Tiwanon Road, Nonthaburi 11000, Thailand
Tel. +66 2 590 7315 Fax. +66 2 591 8489 E-mail : drug@fda.moph.go.th

Food and Drug Administration

Ministry of Public Health, Thailand

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Certificate No.

PART I

The competent authority of Thailand confirms the following;
The manufacturer
Site address

Has been inspected under the national inspection programme in connection with manufacturing licence no. in accordance with

- Ministerial Regulation for Modern Pharmaceutical Manufacturing, B.E. 2546
- Notification of Ministry of Public Health for Good Manufacturing Practice requirements for modern pharmaceuticals manufacturer in accordance with the Drug Act, B.E. 2546

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on , it is considered that it complies with the Thai Good Manufacturing Practice requirements laid down in accordance with the recommendation of the World Health Organization.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and **should be relied upon to reflect the compliance status until** , after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

Type of Medicinal Products

- ☒ Human Medicinal Products
- ☐ Veterinary Medicinal Products
- ☐ Human Investigation Medicinal Products for phase I, II, III clinical trials

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Deputy Secretary-General
For Secretary-General
Food and Drug Administration
Date..........

Certificate No.

PART II

MANUFACTURING OPERATIONS
- authorised manufacturing operations include total and partial manufacturing (including dividing up or packaging), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;   - if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, cytotoxics, cephalosporins, sex hormones, or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.
1. Active pharmaceutical ingredients (List of products)
1.1   1.2 品項

This certificate is intended to be presented only to health authorities, licensed physicians, licensed veterinarians and other licensed practitioners, but not to be used for public advertising purpose.

[redacted]

Mr. Po[illegible]ngmanee

Deputy Secretary-General

For Secretary-General

Food and Drug Administration

FOOD AND DRUG ADMINISTRATION

Date

Bureau of Drug Control, Food and Drug Administration, Ministry of Public Health
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