สำนักงานคณะกรรมการอาหารและยา

Food and Drug Administration

CERTIFICATE OF GMDP COMPLIANCE OF A MANUFACTURER
Good Manufacturing Practice and Good Distribution Practice

Certificate No. 1-2-07-17-23-00034

PART I

The competent authority of Thailand confirms the following:
The manufacturer **THAINAOKA PHARMACEUTICAL CO., LTD.**
Site address **432 MOO 10, KLONGMADUA, KRATHUM BAEN, SAMUT SAKHON 74110, THAILAND**

Has been inspected under the national inspection programme in connection with manufacturing licence no. **2/2560** in accordance with

- Ministerial Regulation for Modern Pharmaceutical Manufacturing, B.E. 2546
- Ministerial Regulation for Modern Pharmaceutical Manufacturing (No. 2), B.E. 2563
- Ministry of Public Health Notification on Good Manufacturing Practice Requirements for Modern Medicines and Amendment of Good Manufacturing Practice Requirements for Traditional Medicines in accordance with the Drug Act, B.E. 2559
- Ministry of Public Health Notification on Rules, Procedures, and Condition for the Distribution of Modern Medicinal Products B.E. 2564

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **19 - 23 JUNE 2023**, it is considered that it complies with the Thai Good Manufacturing Practice requirements laid down in accordance with the recommendation of the Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products (PIC/S GMP) and Good Distribution Practice (PIC/S GDP) for medicinal products.

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 18 JUNE 2026**, 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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(Dr.Withid Sariddeechaikool)
Deputy Secretary-General
For Secretary - General Food and Drug Administration

Date ..... 10 OCT 2023 .....

Medicines Regulation Division, 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 : druginspection@fda.moph.go.th

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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. MANUFACTURING OPERATIONS	
1.1	Sterile products
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids Special Requirements: Penicillin, Cephalosporin
	1.1.2 Terminally sterilized (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.5	Packaging
	1.5.2 Secondary packing
1.6	Quality control testing
	1.6.1 Microbiological: sterility
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations: -
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.

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(Dr. Withid Sariddeechaikool)
Deputy Secretary-General
For Secretary - General, Food and Drug Administration

Date 10 OCT 2023

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