สำนักงานคณะกรรมการอาหารและยา

Food and Drug Administration

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Certificate No. 1-2-07-17-20-00006

PART I

The competent authority of Thailand confirms the following:
The manufacturer **LINARIA CHEMICALS (THAILAND) LIMITED**
Site address **309 BANGPOO INDUSTRIAL ESTATE, SOI 6 C, SUKHUMVIT ROAD, MOO 4, TUMBOL PHRAKSA, AMPUR MUANGSAMUTPRAKAN, SAMUTPRAKAN 10280, THAILAND**

Has been inspected under the national inspection programme in connection with manufacturing licence no. **J. 2/2532** in accordance with

- Ministerial Regulation for Modern Pharmaceutical Manufacturing, B.E. 2546
- 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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **18 – 20 JUNE 2019**, 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 (PIC/S): Guide to Good Manufacturing Practice 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 17 JUNE 2022**, 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

Suchart Chongprasert

(Suchart Chongprasert, Ph.D.)
Director of Bureau of Drug Control

Date 25 OCT 2019

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 : 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. Active Pharmaceutical Ingredients

1.1 Erythromycin Base
1.2 Erythromycin Stearate
1.3 Erythromycin Estolate
1.4 Erythromycin Ethyl Succinate
1.5 Pyrazinamide
1.6 Rifampicin
1.7 Ethambutol Hydrochloride

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.

Suchart Chongprasert

(Suchart Chongprasert, Ph.D.)
Director of Bureau of Drug Control

Date 25 OCT 2019

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