สำนักงานคณะกรรมการอาหารและยา

Food and Drug Administration

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

Certificate No. 1-2-07-17-24-00026

PART I

The competent authority of Thailand confirms the following:
The manufacturer **INPAC PHARMA CO., LTD**
Site address **2,4 SOI ANAMAI - NGAMCHAROEN 24, THAKHAM, BANGKHUNTIAN, BANGKOK 10150, THAILAND**

Has been inspected under the national inspection programme in connection with manufacturing licence no. **2/2536** 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 **3 - 5 and 7 APRIL 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 2 APRIL 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 .....20 DEC 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

Serial No. AA 121490

Certificate No. 1-2-07-17-24-00026

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 penicillins, 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	
1.2	Non-sterile products
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Powders 1.2.1.13 Tablets 1.2.1.17 Other non-sterile medicinal product (Aerosols)
	1.2.2 Batch Certification
1.5	Packaging
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Powders 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal product (Aerosols)
	1.5.2 Secondary packing
1.6	Quality control testing
	1.6.2 Microbiological: non-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 ..... 20 DEC 2023 .....

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Serial No. A 086519