



Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b (2) (b) of Directive 2001/83/EC

Confirmation No. : TH19-0001

1. Name and address of site:
LINARIA CHEMICALS (THAILAND) LTD.
309 Bangpoo Industrial Estate, Soi 6C, Sukhumvit Road, Moo 4,
Tumbol Phraksa, Ampur Muangsamutprakan, Samutprakan 10280, Thailand.
2. Manufacture's license number(s):
J. 2/2532

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU MEDICINAL PRODUCTS FOR HUMAN USE

Active substance (s):	Activity:
Erythromycin Base	Chemical synthesis
Erythromycin Estolate	Chemical synthesis
Erythromycin Ethylsuccinate	Chemical synthesis
Erythromycin Stearate	Chemical synthesis
Ethambutol Hydrochloride	Chemical synthesis
Pyrazinamide	Chemical synthesis

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU;

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection of the plant under (1): *June 18, 2019*

This written confirmation remains valid until: *June 17, 2022*

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

Address of issuing regulatory authority:

Bureau of Drug Control
Food and Drug Administration
Ministry of Public Health
88/24 Tiwanon Road, Nonthaburi 11000
Thailand.

Suchart Chongprasert
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Date: *- 3. DEC. 2019*