

 衛生福利部食品藥物管理署
FDA Food and Drug Administration
Ministry of Health and Welfare, Republic of China (Taiwan)
地址：台北市南港區昆陽街一六一之二號
No.161-2, Kunyang St, Nangang District, Taipei City 115-61, Republic of China (Taiwan)

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.: TFDA-0002187

Issue Date: July 4, 2018

1. Name and address of site: Syn-Tech Chem & Pharm Co., Ltd.

No. 168, Kai Yuan Rd., Hsin-Ying, Tainan City 73055, Taiwan

2. Manufacturer's licence number: (C)0002015

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE ACTIVE SUBSTANCE(S) ARE LISTED IN APPENDIX ON PAGE 2 EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice applicable to this manufacturing plant are Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) for medicinal products PART II (= GMP of WHO/ICH Q7);

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): April 17-18, 2018

This written confirmation remains valid until January 15, 2022

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

Name and function of responsible person:

Ying-Hua (Ellen) Chen

Senior Specialist of GMP Licensing and Certification

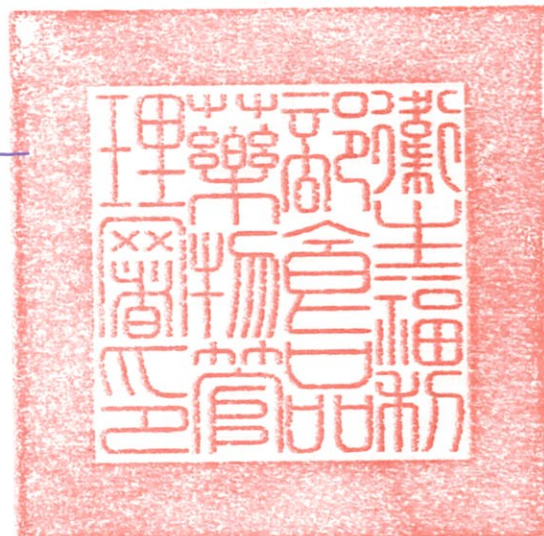
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Signed by



Ming-Shin Lee
Director of GMP Inspectorate

Under the delegated authority of
Shou-Mei Wu, Ph.D.
Director General
Food and Drug Administration,
Ministry of Health and Welfare
Republic of China (Taiwan)



APPENDIX

Active substance(s):	Activity(ies):
Atenolol	Chemical Synthesis, Packaging, Labelling, Quality control
Chlormezanone	Chemical Synthesis, Packaging, Labelling, Quality control
Chlorzoxazone	Chemical Synthesis, Packaging, Labelling, Quality control
Clofibrate	Chemical Synthesis, Packaging, Labelling, Quality control
Cloperastine Hydrochloride	Chemical Synthesis, Packaging, Labelling, Quality control
Crotamiton	Chemical Synthesis, Packaging, Labelling, Quality control
Diclofenac Epolamine	Chemical Synthesis, Packaging, Labelling, Quality control
Diclofenac Diethylamine	Chemical Synthesis, Packaging, Labelling, Quality control
Diclofenac Potassium	Chemical Synthesis, Packaging, Labelling, Quality control
Diclofenac Sodium	Chemical Synthesis, Packaging, Labelling, Quality control
Eperisone Hydrochloride	Chemical Synthesis, Packaging, Labelling, Quality control
Epinephrine	Chemical Synthesis, Packaging, Labelling, Quality control
Epinephrine Bitartrate	Chemical Synthesis, Packaging, Labelling, Quality control
Esomeprazole Sodium	Chemical Synthesis, Packaging, Labelling, Quality control
Granisetron Base	Chemical Synthesis, Packaging, Labelling, Quality control
Granisetron Hydrochloride	Chemical Synthesis, Packaging, Labelling, Quality control
Lansoprazole	Chemical Synthesis, Packaging, Labelling, Quality control
Lamotrigine	Chemical Synthesis, Packaging, Labelling, Quality control
Metaxalone	Chemical Synthesis, Packaging, Labelling, Quality control
Metoprolol Succinate	Chemical Synthesis, Packaging, Labelling, Quality control
Mirtazapine	Chemical Synthesis, Packaging, Labelling, Quality control
Naftopidil	Chemical Synthesis, Packaging, Labelling, Quality control
Nicametate Citrate	Chemical Synthesis, Packaging, Labelling, Quality control
Orciprenaline Sulfate	Chemical Synthesis, Packaging, Labelling, Quality control
Oxazolam	Chemical Synthesis, Packaging, Labelling, Quality control
Oxethazaine	Chemical Synthesis, Packaging, Labelling, Quality control
p-Aminomethylbenzoic Acid	Chemical Synthesis, Packaging, Labelling, Quality control
Phenylephrine Hydrochloride	Chemical Synthesis, Packaging, Labelling, Quality control
Pipethanate Ethobromide	Chemical Synthesis, Packaging, Labelling, Quality control
Pramoxine Hydrochloride	Chemical Synthesis, Packaging, Labelling, Quality control
Rabeprazole Sodium	Chemical Synthesis, Packaging, Labelling, Quality control
Rizatriptan Benzoate	Chemical Synthesis, Packaging, Labelling, Quality control
Sulcaine	Chemical Synthesis, Packaging, Labelling, Quality control
Timolol Maleate	Chemical Synthesis, Packaging, Labelling, Quality control
Tipepidine Hibenzate	Chemical Synthesis, Packaging, Labelling, Quality control
Tolperisone Hydrochloride	Chemical Synthesis, Packaging, Labelling, Quality control
Zolmitriptan	Chemical Synthesis, Packaging, Labelling, Quality control