Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Our Ref. :

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 the Directive 2001/83/EC

Confirmation no.:

1. Name and address of site (including building number, where applicable):

Manufacturer : 廠名

Address : 廠址

Tel :

Fax :

CERTIFIED TRUE COPY

MUHAMMAD HAFEEZ BIN MOHD MUSTHAFA
ASSISTANT DIRECTOR
CENTRE FOR COMPLIANCE & LICENSING
NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH MALAYSIA
PETALING JAYA

2. Manufacturer's licence number(s):[1]

Not Applicable

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

Active substance(s):[2]	Activity(ies):[3]
品項名稱	

Jalan Universiti, P. O. Box 319, 46730 Petaling Jaya, Selangor Darul Ehsan, Malaysia
Tel. : + 603 7883 5400 Faks : + 603 7956 2925 / 7958 1692
http : //www.bpfk.gov.my
Putrajaya Malaysia

CERTIFIED TRUE COPY

MUHAMMAD HAFFIS BIN MOHD MUSTHAFA
ASSISTANT DIRECTOR
CENTRE FOR COMPLIANCE & LICENSING
NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH MALAYSIA
PETALING JAYA

Active substance(s):	Activity(ies):
品项名称	

Jalan Universiti, P. O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia
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Active substance(s):	Activity(ies):
品项名称	

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.[4]

Date of inspection of the plant under (1):

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http : //www.bpfk.gov.my

This written confirmation remains valid until:

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

Address of the issuing regulatory authority:

CERTIFIED TRUE COPY

MUHAMMAD HAFFIS BIN MOHD MUSTHAFA
ASSISTANT DIRECTOR
CENTRE FOR COMPLIANCE & LICENSING
NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH MALAYSIA
PETALING JAYA

Name and function of responsible person:

E-mail, Telephone no. and Fax no.:

Email :

Telephone no. :

Fax no. :

Signature

Stamp of the authority and date

[1] Where the regulatory authority issues a licence for the site. Record 'not applicable' in case where there is no legal framework for issuing of a licence.
[2] Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name).
[3] For example, 'Chemical synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.
[4] qdefect@ema.europa.eu.

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