

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

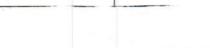
Our Ref. : /

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

Cor	nfirmation no.:		
1.	Name and address of site (including build		ding number, where applicable):
	Address	· 麻 土土	CERTIFIED TRUE COPY
2.	Manufacturer's licence number(s): <sup>1</sup> Not Applicable		MUHAMMAD HAFE: JIN MOHD MUSTHAFA ASSISTAL TO RECTOR CENTRE FOF COMPLL, ICE & LICENSING NATIONAL PHARIL CEUTICAL CONTROL BUREAU MINISTRY SEL ALTH MALAYSIA PETALING JAYA

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):<sup>2</sup> Activity(ies):<sup>3</sup>



品场名4年





Tel.: + 603 7883 5400 Faks: + 603 7956 2977 7958 697

Putrajaya Malaysia



# CERTIFIED TRUE COPY

National Pharmaceutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH MALAYSIA
PELILINGIANA

Active substance(s):

Activity(ies):

品项名物

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Confirmation No:

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## CERTIFIED TRUE COPY

Biro Pengawalan Farmaseutikal Kebangsa MUHAMMAD HAFFIS SIN NOHD MUSTHAFA
National Pharmaceutical Control Bureau

KEMENTERIAN KESIHATAN MALAYSIA CENTRE FOR COMPLIANCE & LICENSING
MINISTRY OF HEALTH MALAYSIANATIONAL PHARMACEUTICAL CONTROL BUREAU

MINISTRY OF HEALTH MALAYSIA

PETALING

		_	
Active	substance	5	):

Activity(ies):

品场名箱

## 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):

Confirmation No:

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Jalan Universiti. P. O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia Faks: + 603 7956 2924 / 7958 1312 Tel.: + 603 7883 5400 http://www.bpfk.gov.my







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

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 OPY

MUHAMMAD HAFFIS BIN MOND MUSTHAFA
ASSISTANT DIRECTOR
CENTRE FOR COMPLIANCE &LICENSING
NATIONAL PHARMACEUTICAL (DITROL BUREAU
MINISTRY OF HEALTH, MALAYSIA
PETALING JAYA

Name and function of responsible person:

ILI,

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

Email

.

Telephone no.

:

Fax no.

Signature

Stamp of the authority and date

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.

<sup>2</sup> Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name).

<sup>3</sup> For example, 'Chemidal synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.

<sup>4</sup> qdefect@ema.europa.eu.

Confirmation No: /

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