



# BADAN PENGAWAS OBAT DAN MAKANAN

Jl. Percetakan Negara No. 23 Jakarta Pusat 10569 Indonesia  
Telp. : 4244691, 42883309, 42883462, 42883279, Fax. : 4243605, 42884208, 4253857  
E-mail : [Infopom@indo.net.id](mailto:Infopom@indo.net.id), Website : [www.pom.go.id](http://www.pom.go.id)

**BADAN POM**

## 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.

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

60R

2. Manufacturer's licence number(s):<sup>1</sup>

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>
	Extraction from natural sources.
	Extraction from natural sources.
	Extraction from natural sources.
	Extraction from natural sources.
	Extraction from natural sources.

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 PIC/S;

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 PIC/S;

And

In the event of critical findings, information on such findings is supplied by the exporting third country without delay to the EU.<sup>4</sup>

*Date of inspection of the plant under (1):*

This written confirmation remains valid until



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

*Address of issuing regulatory authority;*

**BADAN PENGAWAS OBAT DAN MAKANAN**

**NATIONAL AGENCY FOR DRUG AND FOOD CONTROL, REPUBLIC OF INDONESIA**

**Jl. Percetakan Negara no. 23 Jakarta Pusat 10560 Indonesia**

*Name and function of responsible person:*

Director for Control of Production of  
Therapeutic and Household Product

*E-mail, Telephone no., and fax no.:*

Website: [www.pom.go.id](http://www.pom.go.id)

Email:

Phone no.

Fax no. +62 21 4247496

**Signature**



**Stamp of the authority and date**

**BADAN POM**  
28 September 2016

**REPUBLIC INDONESIA**