

REF: 665/149788
Date: 19/2/2018

WRITTEN CONFIRMATION

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.

- Name and address of site (including building number, where applicable):
TEMAD Active Pharmaceutical Ingredients Co., 28th km of Karaj Makhous Road, Tehran, Iran.
- Manufacturer's license number(s):
8904-142

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

| | |
|----------------------|---|
| Active substance(s): | Activity(ies): |
| Pholcodine | Chemical synthesis, purification |

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The principles of good manufacturing practice (GMP) applied to this manufacturing plant are Pharmaceutical Inspection CO-operation / Scheme Guide to Good Manufacturing Practice (PIC/S) 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 related 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):

July 2017

This written confirmation remains valid until:

One year from the date of issue

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

Address of the issuing regulatory authority:

Division of Pharmaceutical and Narcotic Affairs of Ministry of Health
Food and Drug Administration
M O H

FDA Bldg., No. 3, Fakhr-E-Razi St., Enghelab Ave., Tehran 1314715311, IRAN

P.O.Box: 13145-719

Tel: (+98)-21-66466939

Fax: (+98)-21-66469142

Name and function of responsible person:

Dr. Mohammad Soleimani. Qualified Person

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

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For And On Behalf of
Dr. M. Karimi

