

REF: 665/131411

Date: 9/1/2018

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

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

TEMAD Active Pharmaceutical Ingredients Co., 28th km of Karaj Makhsoos Road, Tehran, Iran.

2. Manufacturer's license number(s):

۸۹۰۴۰۱۴۲ - م. الف. د.

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):
Buprenorphine Hydrochloride	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 Adm.

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

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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

