ISLAMIC REPUBLIC OF IRAN
MINSTRY OF HEALTH AND MEDICAL EDUCATION

FOOD AND DRUG ADMINISTRATION

REF: 665/93728
Date: 2/1/2019

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 Makhsous Road, Tehran, Iran.
2. 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):
Methadone 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 2018
This written confirmation remains valid until:
Two years from the date of issue
The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with directive 2001/83/EC.
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. Maryam Esfandyari. Qualified Person
E-mail, Telephone no., and Fax no.:
E- mail: esfandyari@temad.com Tel. No.: +98(26)361008035-6. Fax No.: +98(26)36100834

Dr. Mohammad Abdeh Zadeh
Director General
M. Abdeh Zadeh

Add.: FOOD AND DRUG ADMINISTRATION Bldg.,
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