

REF: 665/12343

Date: 2/5/2020

## 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., 28<sup>th</sup> 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):
Opium tincture 1%	Extraction

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applied to this manufacturing plant are at least equivalent to those laid down in the EU (= 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): February 2019**

**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.

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

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**Name and function of responsible person:**

Dr. Maryam Esfandiyari. Qualified Person

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Dr. Gholam Hossein Mehralian  
Director General

Mehralian

