



Ref: 665/12478 Date: 14/5/2025

Attach: No

## **GMP Certificate**

Manufacturer: TEMAD Co., Active Pharmaceutical Ingredients

Address: 28th km of Karaj Makhsous Road, Alborz, Iran.

**Production Line:** Narcotic Production Line

(Products: Codeine Base, Codeine Phosphate, Codeine HCl, Noscapine Base, Noscapine HCl, Buprenorphine HCl, Buprenorphine HCl (Injection Grade Non-Sterile), Dextromethorphan HBr, Hydrocodone Bitartrate, Opium Powder, Methadone Base, Methadone HCl, Morphine HCl, Morphine Sulphate, Morphine Sulphate (Injection Grade Non-Sterile), Oxymorphone HCl, Oxycodone HCl, Oxycodone HCl (Injection Grade Non-Sterile), Noroxymorphone, Naltrexone Base, Naltrexone Base (Injection Grade Non-Sterile), Naltrexone HCl, Naloxone HCl, Naloxone HCl (Injection Grade Non-Sterile), Papaverine HCl, Papaverine HCl (Injection Grade Non-Sterile), Pholcodine, Thebaine, Tramadol HCl, Tramadol HCl (Injection Grade Non-Sterile))

This is to certify that above-mentioned production line was duly inspected and approved in accordance with Good Manufacturing Practice Principles for active pharmaceutical ingredients which are currently in force in the I.R of Iran.

The manufacturer plant is subject to regular GMP inspections based on PIC/S regulations (at suitable intervals) by the Iranian Food and Drug Administration.

The production line of Narcotic: (Products: Codeine Base, Codeine Phosphate, Codeine HCl, Noscapine Base, Noscapine HCl, Buprenorphine HCl, Buprenorphine HCl (Injection Grade Non-Sterile), Dextromethorphan HBr, Hydrocodone Bitartrate, Opium Powder, Methadone Base, Methadone HCl, Morphine HCl, Morphine Sulphate, Morphine Sulphate (Injection Grade Non-Sterile), Oxymorphone HCl, Oxycodone HCl, Oxycodone HCl (Injection Grade Non-Sterile), Noroxymorphone, Naltrexone Base, Naltrexone Base (Injection Grade Non-Sterile), Naltrexone HCl, Naloxone HCl, Naloxone HCl (Injection Grade Non-Sterile), Papaverine HCl, Papaverine HCl (Injection Grade Non-Sterile), Pholcodine, Thebaine, Tramadol HCl, Tramadol HCl (Injection Grade Non-Sterile)) is in compliance with the cGMP/GMP standards and relevant principles and regulation and complies with the Good Manufacturing Practice requirements of the PIC/S Guidelines.

This certificate is valid until March 2027.

A.Abdollahiasl Pharm.D,Phd IFDA Director General for Pharmaceuticals and Control Materials

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