

ISLAMIC REPUBLIC OF IRAN MINSTRY OF HEALTH AND MEDICAL EDUCATION

REF: 665/40384 28/jul/2018

GMP CERTIFICATE

Manufacturer: Temad Co., Active Pharmaceutical Ingredients

Address: 28th km of Karaj Makhsous Road, Tehran, Iran

Production Line: Narcotic Production Line: (Codeine phosphate, Noscapine, Noscapine HCl, Buprenorphine HCl, Dextromethorphan HBr, Opium powder, Opium tincture 1%, Opium tincture 2%, Methadone HCl, Morphine, Morphine HCl, Morphine sulphate, Oxymorphone, Oxymorphone HCl, Diphenoxylate HCl, Bisacodyl, Naltrexone HCl, Oxycodone HCl, Papaverine crude, Papaverine HCl, Pholcodine, Thebaine, Tramadol HCl)

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 Production Line: (Codeine phosphate, Noscapine, Noscapine HCl, Buprenorphine HCl, Dextromethorphan HBr, Opium powder, Opium tincture 1%, Opium tincture 2%, Methadone HCl, Morphine, Morphine HCl, Morphine sulphate, Oxymorphone, Oxymorphone HCl, Diphenoxylate HCl, Bisacodyl, Naltrexone HCl, Oxycodone HCl, Papaverine crude, Papaverine HCl, Pholcodine, Thebaine, Tramadol HCl) 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 for three years.



TEL: +98-21-66467268 / 66467269

co@fda.gov.ir

FAX: +98-21-66469142 WEBSITE: http://fda.gov.ir

E-Mail: