

# GOVERNMENT OF ANDHRA PRADESH DRUGS CONTROL ADMINISTRATION



From: V. Vijaya Sekhar, M. Pharm., Deputy Director, Drugs Control Administration, Kurnool Region, Kurnool-518003. To: M/s SRI SATYA SAI PALLIATIVE CARE CENTRE, Situated at D.No:1-235, Sai Nagar Circle, Opp. SSS EM School, Puttaparthi-515134, Sathya Sai District - Andhra Pradesh, India.

#### File No. HMF07-19022/7/2024-AD-DCA, Dated: 10.01.2025

Sir,

Sub: A.P. N.D.P.S. Rules, 1986–NDPS-2 License has been extended/renewed for the Period from 01.01.2025 to 31.12.2025 -Regarding.

Ref: 1. Your Application dated: 23-12-2024.

- 2. Inspection report of the Drugs Inspector (FAC), Puttaparthy, dated: 28.12.2024.
- 3. Remarks of the Assistant Director, Ananthapuramu, dated: 04.01.2025 through an e-office.

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With reference to your application cited I forward herewith the Form NDPS-2 License bearing No. NDPS-2/13/KNLR/AP/2023, Dated: 22.07.2023 duly extended/renewed for the period from 01.01.2025 to 31.12.2025 to possess and sell the following NDPS products.

S. No	Drug Name	Strength	Pack	Possession Capacity Per Annum
1.	FENTANYL CITRATE INJ.	50 mcg/ml	2 ml	500 Amps.
2.	MORPHINE SULPHATE INJ.	10 mg/ml	1 ml	5,000 Amps.
3.	MORPHINE SULPHATE INJ.	15 mg/ml	1 ml	5,000 Amps.
4.	METHADONE SYP.	150 ml	1	100 Bottles.
5.	METHADONE IR TABS	5 mg	1	10,000 Tabs.
6.	MORPHINE SULPHATE SR TAB.	10 mg	1	5,000 Tabs.
7.	MORPHINE SULPHATE SR TAB.	20 mg	1	1,000 Tabs.
8.	MORPHINE SULPHATE SR TAB.	30 mg	1	1,000 Tabs.
9.	MORPHINE SULPHATE SR TAB.	60 mg	1	500 Tabs.
10.	MORPHINE SULPHATE IR TAB.	10 mg	1	30,000 Tabs.
11.	MORPHINE SULPHATE IR TAB.	20 mg	1	5,000 Tabs.
12.	MORPHINE SULPHATE IR TAB.	30 mg	1	5,000 Tabs.
13.	MORPHINE SULPHATE IR TAB.	60 mg	1	2,000 Tabs.
14.	FENTANYL TRANSDERMAL PATCHES	12.5 mcg/hr.	1	200 Patches.
15.	FENTANYL TRANSDERMAL PATCHES	25 mcg/hr.	1	150 Patches.
16.	FENTANYL TRANSDERMAL PATCHES	50 mcg/hr.	1	100 Patches.
17.	FENTANYL TRANSDERMAL PATCHES	75 mcg/hr.	1	50 Patches.
18.	FENTANYL TRANSDERMAL PATCHES	100 mcg/hr.	1	30 Patches.



Copy to: the Assistant Director, Drugs Control Administration, Anantahpuramu & Drugs Inspector (FAC), Puttaparthy.



#### GOVERNMENT OF ANDHRA PRADESH DRUGS CONTROL ADMINISTRATION



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From V. VijayaSekhar, M.Pharm., Deputy Director, Drugs Control Administration, Kurnool Region, Kurnool-518003. To M/s SRI SATYA SAI PALLIATIVE CARE CENTRE, Situated at D.No:1-235, Sai Nagar Circle, Opp. SSM EM School, Puttaparthi-515134, Sathya Sai District - Andhra Pradesh, India.

## File No. HMF07-19022/7/2024-AD-DCA, Dated: 06.01.2024

Sir,

Sub: A.P. N.D.P.S. Rules, 1986–NDPS-2 License has been extended/renewed for the Period from 01.01.2024 to 31.12.2024 -Regarding.

Ref: 1. Your Application dated: Nil.

- 2. Inspection report of the Drugs Inspector (FAC), Puttaparthy, dated: 30.12.2023.
- 3. Remarks of the Assistant Director, Ananthapuramu, dated: 03.01.2024 through an e-office.

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With reference to your application cited I forward herewith the Form NDPS-2 License bearing No. NDPS-2/13/KNLR/AP/2023, Dated: 22.07.2023 duly extended/renewed for the period from 01.01.2024 to 31.12.2024 to possess and sell the following NDPS products.

S. No	Drug Name	Strength	Pack	Possession Capacity Per
				Annum
1.	Fentanyl Citrate Inj.	50 mcg/ml	2 ml	500 Amps.
2.	Morphine Sulphate Inj.	10 mg/ml	1 ml	5,000 Amps.
3.	Morphine Sulphate Inj.	15 mg/ml	1 ml	5,000 Amps.
4.	Methadone Syp.	150 ml	1	100 Bottles.
5.	Methadone IR Tabs	5 mg	1	10,000 Tabs.
6.	Morphine Sulphate SR Tab.	10 mg	1	5,000 Tabs.
7.	Morphine Sulphate SR Tab.	20 mg	1	1,000 Tabs.
8.	Morphine Sulphate SR Tab.	30 mg	1	1,000 Tabs.
9.	Morphine Sulphate SR Tab.	60 mg	1	500 Tabs.
10.	Morphine Sulphate IR Tab.	10 mg	1	30,000 Tabs.
11.	Morphine Sulphate IR Tab.	20 mg	1	5,000 Tabs.
12.	Morphine Sulphate IR Tab.	30 mg	1	5,000 Tabs.
13.	Morphine Sulphate IR Tab.	60 mg	1	2,000 Tabs.
14.	Fentanyl Transdermal Patches	2.5 mcg/hr.	1	200 Patches.
15.	Fentanyl Transdermal Patches	25.5 mcg/hr.	1	150 Patches.
16.	Fentanyl Transdermal Patches	50 mcg/hr.	1	100 Patches.
17.	Fentanyl Transdermal Patches	75 mcg/hr.	1	50 Patches.
18.	Fentanyl Transdermal Patches	100 mcg/hr.	1	30 Patches.

Yours faithfully,

DEPUTY DIRECTOR & LICENSING AUTHORITY A.P.N.D.P.S. Rules, 1986. DRUGS CONTROL ADMINISTRATION, KURNOOL REGION, KURNOOL.

**Copy to:** the Assistant Director, Drugs Control Administration, Anantahpuramu District & Drugs Inspector (FAC), Puttaparthy for information.



1.

## GOVERNMENT OF ANDHRA PRADESH DRUGS CONTROL ADMINISTRATION

**FORM NDPS – 2** [Rule 93(1)]



## LICENSE FOR THE POSSESSION AND SALE ON PRESCRIPTION OF MANUFACTURED DRUGS BY CHEMISTS AND MEDICAL PRACTITIONERS.

#### License No. NDPS-2/13/KNLR/AP/2023

## Dated: 22/07/2023.

License is hereby granted to Dr. Bhagavatula Manjula, Authorized Signatory of M/s SRI SATYA SAI PALLIATIVE CARE CENTRE (hereinafter called the Licensee) authorizing them under and subject to the provisions of the Narcotic Drugs and Psychotropic Substances Act, 1985 and the rules made there under to possess and sell or dispense on prescription only manufacture drugs at their Hospital situated at D.No:1-235, Sai Nagar Circle, Opp. SSM EM School, Puttaparthi-515134 in the District of SATHYA SAI ANDHRA PRADESH during the period commencing on 22/07/2023 and ending on 31/12/2023 payment of a fee of Rs.50/- (in words Rupees Fifty only) subject to the conditions herein after mentioned, viz.,

The licensee shall purchase all manufactured drugs to be sold or dispensed under this license from a dealer in manufactured drugs licensed under the Andhra Pradesh N.D.P.S. Act or under the corresponding rules for the time being in force in any part of India or in accordance with condition. He shall not receive or have in his possession any manufactured drugs which are not specified in his condition or which have beenobtained otherwise than as permitted under this condition nor shall he possess them in quantities exceeding those specified below:-

- a) Coca derivatives containing in the aggregate more than \_\_\_\_\_ of Cocaine's,-N.A.
- b) Opium derivatives containing in the aggregate more than of either Morphine, Diacetylmorphine or both -N.A.
- c) Medical hemp exceeding \_\_\_\_\_ in the case of extract, and \_\_\_\_\_ in the case of tinctures-N.A.

S. No	Drug Name	Strength	Pack	Possession Capacity Per Annum
1.	Fentanyl Citrate Inj.	50mcg/ml	2ml	500 Amps.
2.	Morphine Sulphate Inj.	10mg/ml	1ml	5,000 Amps.
3.	Morphine Sulphate Inj.	15mg/ml	1ml	5,000 Amps.
4.	Methadone Syp.	150ml	1	100 Bottles.
5.	Methadone IR Tabs	5mg	1	10,000 Tabs.
6.	Morphine Sulphate SR Tab.	10mg	1	5,000 Tabs.
7.	Morphine Sulphate SR Tab.	20mg	1	1,000 Tabs.
8.	Morphine Sulphate SR Tab.	30mg	1	1,000 Tabs.
9.	Morphine Sulphate SR Tab.	60mg	1	500 Tabs.
10.	Morphine Sulphate IR Tab.	10mg	1	30,000 Tabs.
11.	Morphine Sulphate IR Tab.	20mg	1	5,000 Tabs.
12.	Morphine Sulphate IR Tab.	30mg	1	5,000 Tabs.
13.	Morphine Sulphate IR Tab.	60mg	1	2000 Tabs.
14.	Fentanyl Transdermal Patches	12.5mcg/hr.	1	200 Patches.
15.	Fentanyl Transdermal Patches	25.5mcg/hr.	1	150 Patches.
1 <b>6</b> .	Fentanyl Transdermal Patches	50mcg/hr.	1	100 Patches.
17.	Fentanyl Transdermal Patches	75mcg/hr.	1	50 Patches.
18.	Fentanyl Transdermal Patches	100mcg/hr.	1	30 Patches.

In the case of preparations and admixtures of coca derivatives and opium derivatives, the limit shall be fixed with reference to the Cocaine and Morphine contents, and not with reference to the quantity or bulk of the preparation and the bottle, phials, packages other containers of these preparations or labels affixed to them shall plainly exhibit the actual quantity of the manufactured drugs present in each container or sufficient particulars to admit of the ready calculation of such quantity.

The Licensee, unless be is a Registered Medical Practitioner shall not keep, store, sell or dispense manufactured drugs in any place except in his dispensary described above.

- (a) If the Licensee is a Registered Medical Practitioner, he may carry with him, from place to place manufactured drugs in quantities not exceeding these specified in condition (1) above.
- The licensee shall be responsible for the acts and omissions of every person, appointed to office late for him in carrying on the business of the said dispensary, and of all his servants as if the said acts and omissions were his own.

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- (1). The licensee shall not sell or dispense manufactured drugs except on a bona fide prescription given by himself, if he is Registered Medical Practitioner or by any other Registered Medical Practitioner nor in longer quantity nor to any otherperson than may be specified in the prescription, provided the prescription is not given for the use of prescriber himself.
- (2). A prescription for the supply of manufactured drugs must comply with the following Conditions:-
  - (a) The prescription shall be in writing and shall be dated and signed by a Registered Medical Practitioner with is full name and qualification and address and shall also specify the name and address of the person to whom it is given and the total quantity of the drug to be supplied thereof. If the drug to be supplied be coca derivatives the quantity should not contain more than 389 milligrams of cocaine provided that the licensing authority may be special order authorize the supply of larger quantity considering the circumstances of the particular case.
  - (b) The prescription shall not be given for the use of the prescriber himself.
  - (c) A prescription given by a Registered Dentist shall be only for the purpose of dental treatment of and shall be marked 'For Local Dental Treatment Only' and
  - (d) A prescription given by any Veterinary Surgeon shall be only for the purpose of treatment of animals and shall be marked 'For Animal Treatment Only'.
- (3). When coca derivatives are to be sold or dispensed the licensee shall see that the prescription is marked with the words 'Not to be repeated' and shall not supply coca derivatives more than once on the same prescription except in pursuance of fresh directions only endorsed on the prescription by the approved practitioner by whom it was originally issued and signed with his name in full and dated. Except under a special order made by the Commissioner under rule of the Narcotic Drugs and Psychotropic Substances Rules the quantity so sold or dispensed at one time or to one and the same person in the aggregate on any one day shall not contain more than 389 milligram of cocaine.

- (4). Where opium derivatives or medical hemp are to be sold or dispensed;
- (a) If the prescription does not bear a prescription by a Registered Medical Practitioner stating that it is to be repeated and at what interval of time it is to be repeated and how many times it is to be repeated, the Licensee shall sell the drugs once only on such prescription, and shall retain the prescription provided the shall first warn the Person presenting the prescription that, unless it bears such a superscription as afore said, it will be retained.
- (b) If the prescription bears superscription as aforesaid, and it appears that Opium Derivatives or medical hemp have already been sold on the prescription six times, or such number of times as the prescription is required to be repeated, or that the interval specified in the superscription has been elapsed since prescription was lost dispensed, he shall not sell the drugs on such prescription unless it is further superscripted in that behalf by a Registered Medical Practitioner.
- (5). The licensee shall mark one very prescription dispensed by him his, the address of the premises at which and the date on which it was dispensed. In the case of every preparation made upon a prescription which contains manufactured drugs, the bottle or other respectable or the wrapper or other covering in which such preparation is enclosed shall bear clearly marked upon it the amount and percentage of cocaine or morphine or diacetylmorphine or medicinal hemp contained in such preparation; provided that if the preparation in the form of uniformly divided dossal units, e.g. Pills, powders, tablets, capsules etc., it shall be sufficient if the bottle or other receipt act of the wrapper of other covering in which such preparation is enclosed bears clearly marked upon it the amount and percentage of cocaine or morphine contained in each such dossal unit.
- (6). Where the prescription has to be returned to the person who presents it, the Licensee shall, on the first sale there on, take and keep a copy of it, and on the occasion of each subsequent sale, note thereon the date of the sale and also sign and seal it.
- 4. The Licensee may import, export or transport manufactured drugs by rail or inland post subject to the following conditions:-
  - (a) The parcel of manufactured drug, when sent by post sent by registered parcel.
  - (a a) The parcel whether sent by rail or by post shall be insured.
  - (b) The parcel shall be covered by an authorization issued by the competent authority, at the place to which the parcel is addressed;
  - (c) The parcel shall be accompanied by a declaration showing the names of the consigner and the consignee, the contents of the parcel in detail the number and date of the authorization covering the import, export or transport, as the case may be, and the number of the license, if any, held by the consigner and the consignee.
  - The Licensee shall file and preserve for one year all prescriptions upon which manufactured drugs have been sold or dispensed by him, and shall produce such prescription along with this License and any manufactured drug that may be in his possession for inspection on demand by the Licensing Authority duly authorized by him.

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The Licensee shall maintain a register in such form as may be approved by the Licensing Authority, wherein he shall from time to time record, in respect of the manufactured drugs dispensed by him, the full names and addresses of the Registered Medical Practitioners prescribing the drugs and of the persons for whom they are prescribed. The Licensee shall similarly record in the said register a true account of the kind and quantity of the manufactured drugs dispensed and the calendar month furnish to the Commissioner or Licensing Authority or such other officer as he may appoint in this behalf a copy of the entries made by him in the register during the preceding calendar month.

- (1) This license may be cancelled or suspended by the Licensing Authority at any time:
  - a) for non-payment of duty or fee payable by the licensee;
  - b) for default or violation by himself or by any servant or person acting on his behalf of any of the conditions specified in the license or of the provisions of the Andhra Pradesh Narcotics Drugs and Psychotropic Substances Rules, 1986;
  - c) if the licensee be convicted of any offence under the Andhra Pradesh Narcotic Drugs and Psychotropic Substances Act, 1985 or under the law for the time being in force relating to excise revenue or of a breach of the peace or of any other criminal offence during the currency of the license;
  - d) if the licensee infringes any of the conditions imposed on him by the Narcotic Drugs and Psychotropic Substances Act, 1985 or by the rules in force there under;
  - e) after giving the licensee fifteen days' notice, or if the licensee desires to surrender his license, within fifteen days from the receipt of such notice from him.
  - (2) When such license is cancelled, suspended or surrendered, the licensee shall forth with Make over to the Licensing Authority or such other officer as he may appoint the license together with all the manufactured drugs in his possession.
- 7. The Licensee shall be bound to purchase in such quantity not exceeding that which he is likely to sell in two months and at such rates as the Licensing Authority may direct, any manufactured drugs that may be delivered to the Licensing Authority by any other Licensee whose license expired or has been cancelled or suspended.
- 8. All preparations containing not more than 0.1 % of cocaine or 0.2 % of morphine and any preparation which the Central Government may by notification in the Gazette of India, made in pursuance of finding under Article 8 of the Geneva Convention declare not to be a manufactured drug, maybe imported, exported, transported, possessed and sold without restriction.

Granted this the 22<sup>nd</sup> day of July 2023.

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DEPUTY DIRECTOR & LICENSING AUTHORITY

A.P.N.D.P.S. Rules, 1986. DRUGS CONTROL ADMINISTRATION, KURNOOL REGION, KURNOOL.

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