DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. NDPS-2/TS/MDL/2023-100974 Dated:28/12/2023

To,

M/s MALLAREDDY MEDICALS (O.T PHARMACY) ,

Address **SY.NO.138, D.NO.2-18/2, C/O.MALLAREDDY HOSPITAL, SURARAM MAIN ROAD, SURARAM, QUTHBULLAPUR, MEDCHAL, SURARAM VILLAGE, QUTHBULLAPUR MANDAL, MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500055,TELANGANA STATE,INDIA**

Sir,

Sub:T.S.N.D.P.S.Rules,1986 – Renewal of NDPS License in Form NDPS-2 – Regarding.

Ref: Your application dated:

-x-x-x-

With reference to your application cited, I am herewith forwarding the License in N.D.P.S-2 bearing No.NDPS-2 **TS/MDL/2023-100974,dated:24/02/2023,** duly renewed for the period from: **01/01/2024** is valid upto **31/12/2024** for the quantities of the Narcotic Drugs and Psychotropic Substances mentioned in the License enclosed.

Digitally Signed By
RAMDHAN GUGULOTH
Deputy Director and Licensing Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:28-12-2023 13:36:31 PM

This Document is Digitally Signed. Signature is not required

FORM N.D.P.S-II
[Rule 93(1)]
LICENCE FOR THE MANUFACTURE POSSESSION AND OTHERWISE THAN ON PRESCRITION OF MANUFACTURED DRUGS BY DEALERS

Licence No.NDPS-2/:TS/MDL/2023-100974 Dated:28/12/2023

Licence is hereby granted to of M/s MALLAREDDY MEDICALS (O.T PHARMACY) of following the profession of Pharmacy at SY.NO.138, D.NO.2-18/2, C/O.MALLAREDDY HOSPITAL, SURARAM MAIN ROAD, SURARAM, QUTHBULLAPUR, MEDCHAL, SURARAM VILLAGE, QUTHBULLAPUR MANDAL, MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500055,TELANGANA STATE,INDIA(hereinafter called the Licensee) authorizing him under and subject to the provisions of the Narcotics Drugs and Psychotropic Act, 1985 and the rules made thereunder to possess and sell or dispense, or prescription only, manufactured drugs at his shop/Dispensary situated at SY.NO.138, D.NO.2-18/2, C/O.MALLAREDDY HOSPITAL, SURARAM MAIN ROAD, SURARAM, QUTHBULLAPUR, MEDCHAL, SURARAM VILLAGE, QUTHBULLAPUR MANDAL, MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500055,TELANGANA STATE,INDIA during the period commencing on 01/01/2024 and ending on 31/12/2024 on payment of a fee of Rs.50/- (in words Rupees Fifty only) and subject to the conditions hereinafter mentioned viz:-

1. The licensee shall purchase all manufactured drugs to be sold or dispensed under this license from a dealer in manufactured drugs licensed under the Telangana State NDPS Rules,1986 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 this condition or which have been obtained otherwise than as permitted under this condition nor shall be possess then in quantities exceeding those specified below:-

(a) Coca derivative containing in the aggregate more than of Cocaine, -N.A.
(b) Opium derivatives containing in the aggregate more than – of 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 Size	Quantity
1	Fentanly Citrate Inj	50 mcg/ml	2 ml	10000 amps
2	Morphine sulphate Tabs	10 mg		5000 tablets
3	Fentanyl Transdermal Patches	25 mcg/hr		500 patches
4	Fentanly Citrate Inj	50 mcg/ml	10 ml	2000 amps
5	Morphine Sulphate Inj	10 mg/ml	1 ml	2000 amps
6	Fentanyl Transdermal Patches	50 mcg/hr		500 patches

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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 bottles, 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.

2.(a) The Licensee unless he is a Registered Medical Practitioner shall not keep, store, sell or dispense manufacture drugs in any place except in his dispensary prescribed above.

(b)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.

3. The Licensee shall be responsible for the act and omissions of every person, appointed to officiate 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.

4.(1) The licensee shall not sell or dispense manufactured drugs except on a bonafied prescription given by himself, if he is a Registered Medical Practitioner or by any other Registered Medical Practitioner nor in longer quantity nor to any other person than may be specified in the prescription, provided the prescription is not given for the use of the prescribed 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 his 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 then 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 an Veterinary Surgeon shall be only for the purpose of treatment 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 when 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 the same person in the aggregate on any one day shall not contain more than 389 milligrams of Cocaine.

(4) Where Opium derivatives or medical hemp are to be sold or dispensed:

(a) If the prescription does not bear a subscription 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 may times it is to repeated, the Licensee shall sell the drugs once only on such prescription, and shall retain the prescription provided that the he shall first worn the person presenting the prescription that, unless it bears such a superscription as aforesaid, it will be retained.

(b) If the prescription bears a 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 the prescription was lost dispensed, he shall not sell the drugs on such prescription unless it is further superscribed in that behalf by a Registered Medical Practitioner.

(5) The licensee shall mark on every prescription dispensed by him his name, 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 receiptable 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 hamp contained in such preparation; provided that if the preparation in the form of uniformly divided dosal units, e.g.,pills, powders, tablets, capsules etc., it shall be sufficient if the bottle or other receiptable of the wrapper of other covering in which such preparation is enclosed bears clearly marked upon it the amount and percentage of cocaine of morphine contained in each such dosal unit.

(6) Where the prescription has to be returned to the person who presents it, the Licensee shall, on the first sale thereon, 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.

(7) 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 a post shall be sent by registered parcel.

(aa) The parcel, whether sent by rail or by post, shall be insured.

(b) The parcel shall be covered by an authorization issued by 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 licence 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 alongwith this Licence and any manufactured drug that may be in his possession for inspection on demand by the Licensing Authority duly authorized by him.

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 address 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 balance held by him in stock. The Licensee shall, before the seventh day of each calendar month, furnish to the Commissioner and 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 proceeding calendar month

(8)(1)This licence 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 licence or of the provisions of the Telangana State N.D.P.S.Rules, 1986;

(c) if the Licence, be convicted of any offence under the 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 licence;

(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 thereunder.

(e) After giving the licensee, 15 days notice, or if the licensee, desires to surrender his license, within 15 days from the receipt of such notice from him;

(2) When such licence is cancelled, suspended of surrendered, the licensee shall forthwith made over to the Licensing Authority or such other Officer as he may appoint, the Licence together with all the manufactured drugs in his possession.

(9) 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 who licence has expired or has been cancelled or suspended.

(10) 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 be a manufactured drug, may be imported, exported, transported, possessed and sold without restriction.

Granted this on Date:28/12/2023

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