GOVERNMENT OF PUDUCHERRY
DEPARTMENT OF DRUGS CONTROL
FORM 25-A
[See Rule 70-A]

Loan licence to manufacture for sale [or for distribution of] drugs other than those specified in [Schedules C, C(1) and X]

1. Number of licence and date of issue **21 14 4376** dt. **02.11.2021**

2. **M/s. Generic Health Care Pvt. Ltd., A-69 & A-70, PIPDIC Electronic Park, Thirubuvanai, Mannadipet Commune, Puducherry – 605 107** is hereby granted a loan licence to manufacture the following drugs being drugs other than those specified in [Schedules C, C(1) and X] to the Drugs and Cosmetics Rules,1945, on the premises situated at **R.S No. 4/3, Plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry – 605 009 C/o. Sai Primus Life Biotech Pvt. Ltd.,** under the direction and supervision of the following [competent technical staff]:

(a) Competent technical staff names: **As per the expert Staff endorsed in the licences Of M/s. Sai Primus Life Biotech Pvt. Ltd., Puducherry for Manufacturing and Testing.**
(b) Names of drugs: As per Annexure (each item to be separately specified)

3. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drug manufactured under the licence subject to the conditions applicable to licenses for sale.

4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act, 1940 (23 of1940)and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

02/11/2021

(V. KARTHIKEYAN)
LICENSING AUTHORITY

Date: **02.11.2021**

Conditions of Licence

1. This licence [* * *] shall be kept on the approved premises and shall be produced on the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the [competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to undertake during the currency of the licence to manufacture for sale additional drugs he should apply to the Licensing Authority for the necessary endorsement to the licence as provided in Rule 69-A. This licence will be deemed to extend to the drugs so endorsed.
4. [* * *]
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

GOVERNMENT OF PUDUCHERRY
DEPARTMENT OF DRUGS CONTROL

FORM 28-A

[See Rule 76-A]

Loan Licence to manufacture for sale [or for distribution of] drugs specified in Schedules C and C (1) [excluding those specified in schedule X]

1. Number of licence and date of issue **21 23 4377** dt. **02.11.2021**

2. **M/s. Generic Health Care Pvt. Ltd., A-69 & A-70, PIPDIC Electronic Park, Thirubuvanai, Mannadipet Commune, Puducherry – 605 107** is hereby granted a loan licence to manufacture on the premises situated at **R.S No. 4/3, Plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry – 605 009 C/o. Sai Primus Life Biotech Pvt. Ltd.,** the following drugs being drugs specified in Schedules C and C(1) (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945.

Names of drugs: As per Annexure (each item to be separately specified)

3. Name of approved (Competent technical staff names): **As per the expert Staff endorsed in the licences Of M/s. Sai Primus Life Biotech Pvt. Ltd., for Manufacturing and Testing.**

3-A The license, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act, 1940 (23 of1940)and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

4. The license authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licenses for sale.

5. The license is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

02/11/2021

(V. KARTHIKEYAN)
LICENSING AUTHORITY

Date: **02.11.2021**

Conditions of Licence

1. This licence [* * *] shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. If the licensee wishes to undertake during the currency of the licence to manufacture any drug specified in Schedules C and/or C(1) [excluding those specified in Schedule X] not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 75-A. This licence will be deemed to extend to the items so endorsed.
3. Any change in the [competent technical staff] shall be forthwith reported to the Licensing Authority.
4. [* * *]
5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

GOVERNMENT OF PUDUCHERRY
DEPARTMENT OF DRUGS CONTROL
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ENDORSEMENT No. DDC/Generic L.L@Sai/ADPE/U.IV/2021-22/321

List of Additional Items Permitted to M/sGeneric Health Care Pvt. Ltd., Loan Licensee @ M/s. Sai Primus Life Biotech Pvt. Ltd., R.S. No. 4/3, Plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry – 605009 under License in Form 25A bearing License no. 21 14 4376 dt. 02.11.2021 which shall remain valid perpetually, subject to the deposit of license retention fee periodically as prescribed under the Drugs and Cosmetics Act 1940 and Rules 1945.

CATEGORY - TABLETS

Sl. No.	NAME OF THE PRODUCT	COMPOSITION	
6	Ramipril Tablets BP 2.5 mg RAMIPRIL GH 2.5 (FOR EXPORT USE ONLY)	Each uncoated tablet contains: Ramipril BP Excipients Colour: Approved Colours are used	2.5 mg Q.S.
7	Ramipril Tablets BP 5 mg RAMIPRIL GH 5 (FOR EXPORT USE ONLY)	Each uncoated tablet contains: Ramipril BP Excipients Colour: Approved Colours are used	5 mg Q.S.
8	Ramipril Tablets BP 10mg RAMIPRIL GH 10 (FOR EXPORT USE ONLY)	Each uncoated tablet contains: Ramipril BP Excipients Colour: Approved Colours are used	10 mg Q.S.
9	Moxifloxacin Hydrochloride Tablets BP 400 mg MOXIFLOX- GH 400 mg (FOR EXPORT USE ONLY)	Each film coated tablet contains: Moxifloxacin Hydrochloride BP Equivalent to Moxifloxacin Excipients Colour: Approved Colours are used	400mg Q.S.
10	Ramipril and Hydrochlorothiazide Tablets 5 mg + 12.5 mg RAMITHIAZIDE 5 MG/ 12.5 MG (FOR EXPORT USE ONLY)	Each uncoated tablet contains: Ramipril BP Hydrochlorothiazide BP Excipients Colour: Approved Colours are used	5mg 12.5mg Q.S.
11	Ramipril and Hydrochlorothiazide Tablets 10 mg + 12.5 mg RAMITHIAZIDE 10 MG/ 12.5 MG (FOR EXPORT USE ONLY)	Each uncoated tablet contains: Ramipril BP Hydrochlorothiazide BP Excipients Colour: Approved Colours are used	10 mg 12.5mg Q.S.
12	Tadalafil Tablets USP10 mg TADAGEN 10 MG (FOR EXPORT USE ONLY)	Each film coated tablet contains: Tadalafil USP Excipients Colour: Approved Colours are used	10 mg Q.S.
13	Carbimazole Tablets BP 5mg CARBIGEN 5 (FOR EXPORT USE ONLY)	Each uncoated tablet contains: Carbimazole BP Excipients Colours: Approved Colours used	5 mg Q.S.
14	Carbimazole Tablets BP 20mg CARBIGEN 20 (FOR EXPORT USE ONLY)	Each uncoated tablet contains: Carbimazole BP Excipients Colours: Approved Colours used	20 mg Q.S.

31/12/2021

(V. KARTHIKEYAN)
LICENSING AUTHORITY

Place: Puducherry
Date: 31 DEC 2021