E-mail

DIRECTORATE OF DRUGS CONTROL : ODISHA: BHUBANESWAR

No. 2043 **/ DC-I-Mfg(A)-Angul-04/2020 , Bhubaneswar Dt.** 02.05.2020

To

Shri Prakash Chandra Dhal, Proprietor,

M/s Sai Ram Oxygen,

At- Rantalei,

P.O./Dist.- Angul.

Sub: Enforcement of D & C Act and Rules thereunder- Issue of licence for manufacture for sale or for distribution of drugs in Form-25 bearing No. 853 dt. 02.05.2020.

Ref: Your application dt. **23.04.2020 and 28.04.2020.**

Sir,

In inviting reference to your application dated **23.04.2020 and 28.04.2020**, you are hereby permitted to manufacture for sale or for distribution of 01 (One) item of drug (Oxygen IP) under manufacturing Drug Licence in Form 25 bearing No. **853** in public interest keeping in view of the sudden outbreak of Corona Virus (COVID-19) pending joint inspection of the premises and other formalities. This licence has been issued to expedite the production of **Oxygen IP** and to ensure its availability and supply for medical use across the country in pursuance of letter dated 07.04.2020 in File No. DCGI/Misc/2020(96) of the Drugs Controller General (India). The original licence in Form 25 is sent herewith receipt of which may be acknowledged. The validity of licence issued is subject to further instructions/ guidelines, if any issued by the Government in future.

You are required to follow the provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder and supply the item approved under the licence only to the Government as per requirement subject to the following conditions.

1. To label & pack the drug in accordance to the provisions of Indian Pharmacopoeia and the Drugs and Cosmetics Rules.
2. To submit test report of Raw materials & finished product of all batches of the above item from your own Laboratory in the last week of every month.
3. To fulfill the statutory requirements of other law in force and to follow instruction(s) issued by Government from time to time in respect of manufacture/ sale/ distribution/ price, etc. of the item.

Yours faithfully,

Drugs Controller, Odisha
Licensing Authority

Drugs Controller, Odisha
(Licensing Authority)

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Memo No..... **Dt.....**

Copy forwarded to the Drugs Inspector, Angul Range, Angul for information and necessary action. She is instructed to provide necessary assistance to the firm as and when required for early availability and supply of the approved item for medical purpose.

-Sd-

Drugs Controller, Odisha

(P.T.O.)

Memo No..... **Dt.....**

Copy forwarded to the Deputy Drugs Controller, Western Zone, Sambalpur for information and necessary action. He is requested to provide necessary assistance to the firm as and when required for early availability and supply of the approved item for medical purpose.

-Sd-
Drugs Controller, Odisha

Memo No..... **Dt.....**

Copy submitted to the Collector & District Magistrate, Angul for kind information and necessary action.

-Sd-
Drugs Controller, Odisha

Memo No..... **Dt.....**

Copy submitted to the M.D., O.S.M.C.L., Bhubaneswar for her kind information and necessary action.

-Sd-
Drugs Controller, Odisha

Memo No..... **Dt.....**

Copy submitted to the Principal Secretary to Government of Odisha, Health and Family Welfare Department for his kind information and necessary action.

-Sd-
Drugs Controller, Odisha

Memo No..... **Dt.....**

Copy submitted to the Principal Secretary to Government of Odisha, Industries Department for kind information and necessary action.

-Sd-
Drugs Controller, Odisha

Memo No..... **Dt.....**

Copy submitted to the Drugs Controller General India, CDSCO HQ, Kotla Road, New Delhi for his kind information and necessary action.

-Sd-
Drugs Controller, Odisha

Directorate of Drugs Control Admn.
Licensing Authority
(Drugs & Cosmetics)
Date.....
Odisha, Bhubaneswar

FORM-25
[See Rule 70]

Licence of manufacture for sale or for distribution of drugs other than those specified in Schedule C,C(1) and X

Number of licence and date of issue: - **853** Dated **02.05.2020**

1. **Sri Prakash Chandra Dhal (Prop.) of M/s Sai Ram Oxygen** is hereby licensed to manufacture the following categories of drugs than specified in Schedule C, C(1) and X to the Drugs and Cosmetics Rules 1945, on the premises situated at **Rantalei, Plot No. 3278/4591 & 3268, Khata No. 505/789, 505/726, P.O./ Dist.- Angul** under the following competent technical Staff.

   (a) Name of approved competent technical staff

   (i) Harisankar Samanta, B.Tech(Mechanical Engineering) and experience (In-charge of Manufacturing)

   (ii) Rajashree Rajanandini, M.Sc. with experience (In-charge of Quality Control)

   (iii) Soubhagya Dhal, Diploma (Electrical Engineering) and experience (In-charge of Manufacturing)

   (b) Names of drugs**: Oxygen IP**

2. The licence authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.
3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) 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 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.

Date : 02.05.2020

Drugs Controller, Odisha
Licensing Authority

Drugs Controller, Odisha
(Licensing Authority)

Conditions of Licence

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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. Any change in the competent technical staff named in the licence shall be henceforth reported to the Licensing Authority.
3. If the licensee wants to manufacture for sale additional items of drugs not included above, he should apply to the Licencing Authority for the necessary endorsement as provided in the Rule 69 (5) . This licence will be deemed to extend the categories so endorsed.
4. The licensee shall inform the Licencing 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 changes 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.]

LTR