

**GOVERNMENT OF KARNATAKA  
DRUGS CONTROL DEPARTMENT**

No. DCD/MFG/SR-1283/16-17

Office of the Drugs Controller  
for the State of Karnataka  
Palace Road, Bangalore 01.

Date:

20 FEB 2017

To,  
M/s. Syngene International Ltd.,  
Unit S18 FC 2nd Floor & S19,  
Biocon Park, Plot No. 2, 3 & 4,  
IV Phase, Bommasandra Industrial Area,  
Jigani Link Road, Bangalore – 560 099.

Sir,

Sub: Drugs & Cosmetics Act, 1940 & Rules 1945 – Application for grant  
of fresh manufacturing License.

Ref: Your application dated 13.01.2017 for grant of fresh manufacturing  
license.

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I am to state that you are granted manufacturing licence in Form 25 bearing No. KTK/25/656/2016, dated 18.02.2017 for the manufacture of approved drugs. The licence is valid from 18.02.2017 to 17.02.2022.

You are required to intimate the date of commencement of manufacture of the said products and to send the test reports of each product duly analysed at an approved laboratory.

You should comply with Drugs (Prices Control) Order 2013 as applicable to your unit and also to the price fixed by the NPPA for the product permitted under this letter, if any.

The packing of the product shall be in conformity with the provisions of Schedule P-1 as applicable.

You are requested to submit the specimen labels/cartons of the products in triplicate complying with the labeling provisions to this office for records.



Yours faithfully,

**(BHAGOJI. T. KHANAPURE)**  
DRUGS CONTROLLER &  
LICENSING AUTHORITY

**FORM – 25**  
(See Rule 70)

Licence to 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: KTK/25/656/2016, dated 18.02.2017

1. M/S. SYNGENE INTERNATIONAL LTD. is hereby licensed to manufacture the following categories of drugs, being drugs other than those specified in Schedules C and C(1) and X to the Drugs and Cosmetics Rules, 1945, on the premises situated at BIOCON PARK, UNIT S18 FC 2<sup>ND</sup> FLOOR & S19, PLOT NO. 2, 3 & 4, IV PHASE, BOMMASANDRA INDL. AREA, JIGANI LINK ROAD, BANGALORE – 560 099.
2. under the direction and supervision of the following Competent Technical Staffs:

(a) **Competent Technical Staff (Names):**

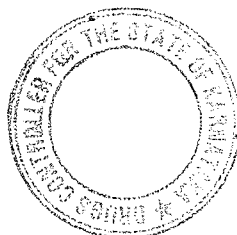
- Dr. T. Geetha - M.Pharm, Ph.D. - Manufacturing
- Sri. Venkatesh S Chouhan - M.Pharm - Testing
- Sri. Guruprasad Anand - M.Sc - Testing

(b) **Name of the Drugs (each item to be separately specified):**

*'As per the list of approved drugs enclosed'*

3. The licence authorises 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.
4. The licence shall be in force from 18.02.2017 to 17.02.2022.
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.

Date: **18.02.2017**

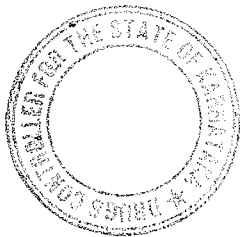


**(BHAGOJI. T. KHANAPURE)**  
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KARNATAKA

LIST OF PRODUCTS PERMITTED TO MANUFACTURE BY M/S. SYNGENE INTERNATIONAL LTD, BIOCON PARK, UNIT S18 FC 2ND FLOOR & S19, PLOT NO. 2, 3 & 4, IV PHASE, BOMMASANDRA INDL. AREA, JIGANI LINK ROAD, BANGALORE – 560 099. UNDER LICENCE IN FORM 25 BEARING NO. KTK/25/656/2016, DATED 18.02.2017. THE LICENCE IS VALID FROM 18.02.2017 TO 17.02.2022 VIDE REF. NO. DCD/MFG/SR-1283/16-17. \*\*\*\*\*

Sl. No.	Name of the Products	Composition
1.	Metformin Extended Release Tablets USP 1000mg	Each Uncoated Extended Release tablet Contains: Metformin Hydrochloride USP equivalent to Metformin 1000mg
2.	Metformin Extended Release Tablets IP 1000mg	Each Uncoated Extended Release tablet Contains: Metformin Hydrochloride IP equivalent to Metformin 1000mg

APPROVED TWO PRODUCTS ONLY AS MENTIONED ABOVE



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