Form CT-09
[See rules 47, 48, 49, 50 and 51]

GRANT OF REGISTRATION OF BIOAVAILABILITY OR BIOEQUIVALENCE STUDY CENTRE

Registration No. **BABE/2019/0016**

The Central Licencing Authority hereby register **M/s Sipra Labs Limited, 7-2-1813/5/A, Industrial Estate, Sanath Nagar, Hyderabad-500018, India** for conduct of bioavailability and bioequivalence studies of New Drugs and Investigational New Drugs as specified in the New Drugs and Clinical Trial Rules, 2019.

2. This registration is subject to the condition prescribed in chapter VII of New Drugs and Clinical Trial Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date: 26 DEC 2019

Dr V G SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Central Licensing Authority
Stamp

Note: The registration shall remain valid for a period of five years from the date of its issue, unless suspended or cancelled.

सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhawan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. 4-14/2019/BA-BE/011

Dated: 26 DEC 2019

To,

M/s Sipra Labs Limited,
7-2-1813/5/A, Industrial Estate,
Sanath Nagar, Hyderabad-500018 India

Sir,

With reference to your application No. SLL/BE/01/2019 dated 28/08/2019; please find enclosed herewith the registration certificate in Form CT-09 bearing Registration No. **BABE/2019/0016** under the provisions of New Drugs and Clinical Trial Rules, 2019, for the Bioavailability/Bioequivalence study centre having Clinical facility with **80 beds** and Bio-analytical facility at **M/s Sipra Labs Limited., 7-2-1813/5/A, Industrial Estate, Sanath Nagar, Hyderabad-500018, India**

The registration in Form CT-09 is subject to the following conditions:

(i) The registration shall remain valid for a period of five years from the date of its issue, unless suspended or cancelled. However there will be periodic assessment of the study centre.

(ii) The centre shall maintain the facilities with adequately qualified and trained personnel as specified in the Fourth Schedule of the New Drugs and Clinical Trial Rules, 2019 for performing its functions.

(iii) The centre shall initiate any bioavailability study or bioequivalence study of any new drug or investigational new drug in human subjects after approval of the protocol and other related documents by the Ethics Committee for clinical trial and permission of such study granted by the Central Licencing Authority;

(iv) where the bioavailability or bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from another Ethics Committee for clinical trial registered under rule 8:

Provided that the approving Ethics Committee accepts the responsibility for the study at the centre and, both the approving Ethics Committee and the centre, are located within the same city or within a radius of fifty kms of the centre;

(v) the Central Licencing Authority shall be informed about the approval of the Ethics Committee for clinical trial;

(vi) Bioavailability or bioequivalence study of investigational new drug shall be registered with the Clinical Trial Registry of India before enrolling the first subject for the study.

(vii) Study shall be conducted in accordance with the approved protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and provisions of Drugs and Cosmetics Act, 1940 and New Drugs and Clinical Trial Rules, 2019.

(viii) In case of termination of any such study prematurely, the detailed reasons for such termination shall be communicated to the Central Licencing Authority immediately.

(ix) Any report of serious adverse event occurring during study to the subject of such study shall, after due analysis, be forwarded to Central Licencing Authority within fourteen days of its occurrence in the format as specified in Table 5 of the Third Schedule and in compliance with the procedures as specified in rule 42.

(x) In case of an injury to the study subject during study, the complete medical management and compensation in the case of study related injury shall be provided in accordance with the provisions of Chapter VI and details of compensation paid to the trial subject in such cases shall be intimated to the Central Licencing Authority within thirty days of receipt of the order.

(xi) In case of death, permanent disability, injury other than death and permanent disability, as the case may be, of a study subject, compensation shall be provided in accordance with the provisions of Chapter VI and details of compensation paid to the trial subject or his legal heir, as the case may be, in such cases shall be intimated to the Central Licencing Authority within thirty days of receipt of the order.

(xii) If there is any change in constitution or ownership of the bioavailability and bioequivalence study centre, the centre shall intimate about the change in writing to the Central Licencing Authority within thirty days of such change.

(xiii) The study centre shall maintain data, records, and other documents related to the conduct of the bioavailability or bioequivalence study for a period of five years after completion of such study or for at least two years after the expiration date of the batch of the new drug or investigational new drug studied, whichever is later.

(xiv) The bioavailability and bioequivalence study centre shall allow any officer authorized by the Central Licencing Authority who may be accompanied by an officer authorized by State Licencing Authority to enter the premises with or without prior notice, to inspect any record, statistical observation or results or any documents related to bioavailability study and bio-equivalence study and furnish information to the queries raised by such authorized person, in relation to the conduct of the said study.

(xv) In case an Ethics Committee of a bioavailability or bioequivalence study centre rejects the approval of the protocol, the details of the same should be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the bioavailability or bioequivalence study at the same site.

(xvi) The bioavailability or bioequivalence study shall be initiated by enrolling the first subject within a period of one year from the date of grant of permission, failing which prior permission from the Central Licencing Authority shall be required

Kindly acknowledge receipt of this letter and its enclosure.

Yours faithfully,

Central Licensing Authority
Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

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[See rules 47, 48, 49, 50 and 51]

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