Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.:011-23236965
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FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 22 JUN 2021

To,

M/s. Mankind Pharma,
Bangalore Depot,
No. 283, Gr and 1st Floor,
Bommasanbra, Jigani Link Road,
Anekal Taluk, Jigani, Bangalore-560105.

Subject: **Permission to conduct Phase IV clinical trial with the FDC of (Flupentixol 0.5 mg + Melitracen 10 mg tablets (Vide protocol no. CRB/CT-001/2018, version no. 3.1, dated: 01.12.2020)-regarding.**

CT No. **CT-06-63/2021**

Sir,

Please refer to your letter no. nil dated 28.12.2020 on the subject mentioned above. This Directorate has no objection to your conducting clinical trial with the said drug under the supervision of following investigators mentioned and as per the **Vide Protocol No. CRB/CT-001/2018, version no. 3.1, dated: 01.12.2020** submitted to this Directorate.

1. Prof (Dr) Dilip Kumar Mondal, RG Kar Medical College and Hospital, 1 Khudiram Bose Sarani, Kolkata-700004, West Bengal.
2. Dr. Kulkarni Krishnaji Siddo, Oyster & Pearl Hospital (Phandis Clinic Pvt. Ltd.), 5th Floor, Room No. 504, 1671-75, Ganeshkhind Rd, Shivajinagar, Pune-411005, Maharashtra.
3. Dr. Malay Kant Singh, KRM Hospital and research Centre, 3/92-93, Vijayant Khand, Gomti Nagar, Lucknow-226010, U.P.
4. Dr. Nischol Raval, Sahyadri Super Speciality Hospital Nagar Road Survery No. 185A, Shastri Nagar, Near MSEB Office Yerwada, Nagar Road, Pune-411006, Maharashtra.
5. Prof (Dr.) Pradip Kumar Saha, Institute of Psychiatry, 244, AJC Bose Road, Kolkata-700020, West Bengal.
6. Dr. Ramesh Kumar Mahendru, Mahendru Psychiatric Centre, 117/40, Sarvodaya Nagar, Kanpur-208005.
7. Dr. Sabhesan Shivam, Apollo Speciality Hospitals, Lake View Road, K. K. Nagar, Madurai, Tamil Nadu-625020.
8. Dr. Nagapurkar Umesh Sureshrao, Shree Siddhivinayak Maternity & Nursing Home, Unity Complex, 2nd Floor, Opp. K.T.H.M., College, Gangapur Road, Nasik-422002, Maharashtra.

The clinical trial permission is subject to the following conditions:-

I. Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;

II. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

   i. Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

XV. The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

XVI. The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

XVII. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

XVIII. The formulation intended to be used in the clinical trial study shall be manufactured under GMP conditions using validated procedures.

XIX. **ECG is required to be done at the end of the treatment.**

XX. **It was noticed that following statement mentioned in the ICD (Informed Consent Document)is not as per the protocol -**
"If you will be assigned to test arm, your participation in study will be for 12 months. However, if you will be assigned to standard treatment arm, your duration of participation will be 2 months." The firm shall make necessary corrections accordingly and proceed.

XXI. **Phase IV clinical trial should be completed within 24 months and report should be submitted to CDSCO for further necessary action.**

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:-
All Zonal/Sub Zonal offices of CDSCO.