

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

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

01 OCT 2021

To,

M/s. Dr. Reddy's Laboratories Ltd.,
Integrated Product Development, Innovation Plaza,
Survey No. 42, 45 & 46, Bachupally (Village),
Bachupally (Mandal), Medchal-Malkajgiri District,
Hyderabad-500090, Telangana.

Subject: Permission to conduct Phase II clinical trial with the FDC of Naltrexone Hydrochloride + Zonisamide (32mg + 91mg, 32mg + 182mg, 32mg + 273mg & 32mg + 364mg) sustained release capsules (Vide protocol no. DRL-INDNDA01-ZN/2018, version no. 2.0, dated: 20.03.2019)-regarding.

Dear Sir,

With reference to your letter No. DRL/NRA/0563-20 dated 04.03.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-169/2021** under the provision of Drugs and Cosmetics Act and Rules. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully,



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

CONDITIONS OF PERMISSION

- 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;
 - ii. Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;
- III. In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**

Permission no.: CT-06-169/2021

1. The Central Licencing Authority hereby permits **M/s. Dr. Dr. Reddy's Laboratories Ltd., Integrated Product Development, Innovation Plaza, Survey No. 42, 45 & 46, Bachupally (Village), Bachupally (Mandal), Medchal-Malkajgiri District, Hyderabad-500090, Telangana.** (Name and full address with contact details of the applicant) to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. DRL-INDNDA01-ZN/2018, version no. 2.0, dated: 20.03.2019**) in the below mentioned clinical trial sites.
2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date:

01 OCT 2021

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Naltrexone Hydrochloride + Zonisamide (32mg + 91mg, 32mg + 182mg, 32mg + 273mg & 32mg + 364mg) sustained release capsules
Therapeutic class:	Naltrexone (Opioid antagonist) Zonisamide (Antiepileptic)
Dosage form:	Capsule
Composition:	Naltrexone Hydrochloride + Zonisamide (32mg + 91mg, 32mg + 182mg, 32mg + 273mg & 32mg + 364mg) sustained release capsules
Indications:	For the treatment of obesity.

Details of clinical trial site:

Names and address of clinical trial site:	As per annexure- A
Ethics committee details:	As per annexure- A
Name of principal investigator:	As per annexure- A

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Central Licencing 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

Permission no.: CT-06-169/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Nikhil Madhusudan Bhagwat	Department of Endocrinology, 4th floor, Room No: 419, College building, T. N. Medical College & B.Y.L Nair Ch. Hospital, Dr A.L. Nair Road, Mumbai Central, Mumbai – 400 008, India.	Institutional Ethics Committee Topiwala National Medical College and B.Y.L. Nair Charitable Hospital, Ground Floor G Building, A.L. Nair Road, Mumbai Central-400008, India. ECR/22/Inst/Maha/2013/RR-16
2	Dr. Rakesh Kumar Sahay	Department of Endocrinology, 2nd floor, Golden Jubilee Block, Osmania Medical College and Osmania General Hospital, Afzalgunj, Hyderabad, Telangana-500 012, India.	Ethics Committee, Osmania Medical College, Koti, Hyderabad-500 059, India. ECR/300/Inst/AP/2013/RR-16
3	Dr. Naval K Vikram	Department of Medicine, All India Institute of Medical Sciences, Ansari Nagar, New Delhi- 110029	Ethics Committee All India Institute of Medical Sciences, Room No.: 102, 1st Floor, Old O.T. Block, Ansari Nagar, New Delhi- 110029, India. ECR/538/Inst/DL/2014/RR-17
4	Dr. Nitin Kapoor	Department of Endocrinology, Diabetes and Metabolism, Christian Medical College, Vellore-632 004, Tamil Nadu, India	Ethics Committee Silver Research Office, First Floor, Carman Block, Christian Medical College, Vellore-632 002, Tamil Nadu, India. ECR/326/Inst/TN/2013/RR-16
5	Dr. Ashraf Ganie	Department of Endocrinology and Metabolism, SKIMS, Sher-Kashmir, Srinagar-190011	Ethics Committee, Sher- I – Kashmir Institute of Medical Science, Room 1108, 1st floor, Administrative block, SKIMS Saura, Srinagar, 190011 Jammu & Kashmir, India ECR/799Inst/JK/2016
6	Dr. Bipin Setthi	Department of Endocrinology, CARE Outpatient Centre, Banjara Hills, Hyderabad	Institutional Ethics Committee, Care Hospital(IECGH) Care Convergence Centre, H. No. 8-2-595/2/B, Road No. 10, Banjara Hill, Hyderabad, Andhra Pradesh, India ECR/94/Inst/AP/2013/RR-16
7	Dr. Lakshmi Lavanya	Department of Endocrinology, Global Hospital, Hyderabad, 500004	Institutional Ethics Committee, Global Hospitals, 6-1-1070/1 to 4, Lakdi Ka Pul, Hyderabad-500004 India ECR/158/Inst/AP/2013/RR-16
8	Dr. Dinesh Jain	Department of Medicine, Dayanand Medical College & Hospital Ludhiana-141001, Punjab	Drug Trial Ethics Committee Basement, Hero DMC Heart Institute Opp. Library, Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana - 141001, Punjab India ECR/101/Inst/PB/2103/RR-16

9	Dr. Sudip Chatterjee	Park Clinic, Endocrinology department, 6th floor, 4-Gorky Terrace 700017, Kolkata	Park Clinic Ethics Committee, Park Clinic, 4 Gorky Park Clinic, Kolkata-700017, West Bengal India Terrace, WEST BENGAL ECR/618/Inst/WB/2014/RR-17
10	Dr. Ganapathi Bantwal	St. John's Medical College & Hospital, Department of Endocrinology, St. John's Medical College & Hospital, Sarjapura Road- Bangalore-560034	Institutional Ethical Committee St. John's Medical College, Room No. 116, Next to Cardinal Gracias Hall, Ground Floor, Old College Building, India 560034 Bangalore, Karnataka ECR/238/Inst/KA/2013/RR-16
11	Dr. Suresh Damodharan	Sri Ramakrishna Hospital 395, Sarojini Naidu Road, Siddhapudhur, Coimbatore-641044	Ethics Committee Sri Ramakrishna Hospital Siddhapudhur, Coimbatore-641044 395, Sarojini Naidu Road, Tamilnadu, India ECR/690/Inst/TN/2014/RR-18

Place: New Delhi

Date:

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V. G.

Central Licencing Authority

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