

Nil

File No. FDC/CT/21/000015 ✓

Govt. of India

Directorate General of Health Services
Central Drug Standard Control Organization
(FDC Division)

Tele. No. :011-23236965

Fax No. :011-23236973

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

To,

M/s. Cadila Pharmaceuticals Limited,
1389-Trasad Road, Dholka
Ahmedabad-382225, Gujarat.

24 SEP 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Betamethasone dipropionate Ph. Eur 0.643mg + Calcipotriol anhydrous Ph. Eur 50mcg cutaneous spray (Vide protocol no. CRSC20008, version no. 02, dated: 04.06.2021)-regarding.

Dear Sir,

With reference to your online application submitted in CT-04 on dated 09.09.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-159/2021 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;
- IV. The Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
- V. Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;

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-06-159/2021

1. The Central Licencing Authority hereby permits **M/s. Cadila Pharmaceuticals Limited, 1389-Trasad Road, Dholka, Ahmedabad-382225, Gujarat** (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. CRSC20008, version no. 02, dated: 04.06.2021**) 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:

12 4 SEP 2021

Annexure:

Details of new drug or investigational new drug:

Vhr
**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

Names of the new drug or investigational new drug:	Betamethasone dipropionate Ph. Eur 0.643mg + Calcipotriol anhydrous Ph. Eur 50mcg cutaneous spray
Therapeutic class:	<ul style="list-style-type: none"> • Betamethasone Dipropionate - Corticosteroid • Calcipotriol - Vitamin D3 derivative
Dosage form:	Cutaneous spray
Composition:	Betamethasone dipropionate Ph. Eur 0.643mg + Calcipotriol anhydrous Ph. Eur 50mcg cutaneous spray
Indications:	For the treatment of mild to moderate plaque psoriasis

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

Permission no.: CT-06-159/2021

S.No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. Saurabh Kapadia	Hitech Multispecialty Hospital , Sector 3D, Plot No. 1180, Gh Road, Nr. Gh, 11 by 2 Bus Stand, Gandhinagar, Gujarat 382003	Hi-Tech Ethics Committee
2	Dr. Nipul Vara	Medical college Baroda and Shri Sayaji Rao General Hospital, Jail Road, (Indira Avenue), Vadodara-390001, Gujarat	Institutional Ethics Committee for Human Research
3	Dr. Jayanta Kumar Barua	Calcutta School of Tropical Medicine , Institutional Ethics Committee, Calcutta School of Tropical Medicine, 108, chittaranjan Avenue, Kolkata – 700073, West Bengal	Clinical Research Ethics Committee
4	Dr. Perumal M	Panimalar Medical College Hospital and Research, Institute Varadharajapuram, Poonamallee Chennai – 600123, Tamilnadu	PMCHRI-IHEC
5	Dr. Sharmila Patil	Dr. D.Y. Patil Hospital & Research Center, Sector 5, Nerul, Navi Mumbai -400706, Maharashtra	Institutional Ethics Committee
6	Dr. Nikita Jadhav	Priyadarshani Nursing Home, 201-208. M-Baria Estate, Kargil nagar Road, Opp. Manvel Pada, Talav, Virar (East) Dist - Palghar, 401305, Maharashtra	IEC of New Health Care Nursing Home
7	Dr. Neha Sharma	Lotus Multispecialty Hospital, Room No. 2, 2nd Floor, Beside, Swastik School Motera Stadium Road , Motera Sabarmati, Gujarat - 380005	Lotus Ethics Committee
8	Dr. Ishad Aggarwal	Life Line Diagnostic Center cum Nursing Home, 4A, Wood Street, Kolkata- 700016, West Bengal	IEC of Life Line Diagnostic Center cum Nursing Home
9	Dr. L Eshwari	Bangalore Medical College & Research Institute. Fort, Krishna Rajendra Rd, Bengaluru, Karnataka 560002	Ethical Committee, Bangalore Medical College and Research Institute, KR Road, Fort Bangalore 560002
10	Dr. Sharath Kumar BC	Kempegowda Institute of Medical Sciences, Athibabbe Road, 30th Main Rd, near BDA Shopping Complex, Banashankari Stage II, Banashankari, Bengaluru, Karnataka 560070	KIMS Institutional Ethics Committee, KIMS College, Banashankari 2nd, stage, Bangalore 560070
11	Dr. Khushali Shah	V.S. General Hospital, 605, Paldi Road, Madalpur Gam, Paldi, Ahmedabad, Gujarat 380006	Institutional Ethics committee, Municipal Medical college, Ellisbridge, Ahmedabad-380006, Gujarat, Ahmedabad
12	Dr. Usha Khemani	Grant Govt. Medical College & Sir J. J. Group of Hospitals, J J Marg, Nagpada, Mumbai Central, Mumbai, Maharashtra 400008	Institutional Ethics committee, Grant Government Medical college and Sir JJ Group of Hospitals, Byculla, Mumbai-400008, Maharashtra, India

Place: New Delhi

Date:

24 SEP 2021


Central Licencing Authority
Stamp

Dr. V. G. SOMANI

Drugs Controller General (India)

Dir. General of Health Services

Ministry of Health and Family Welfare

Plot No. 1, Kotta Road, I.T.O.

New Delhi-110002