सत्यमेव जयते

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

File No. CT/24/000138

To,

M/s Ethicare Clinical Trial Services (OPC) Pvt. Ltd.,
F-Block, 1101-1110, PNTC Building, Radio Mirchi Road,
Vejalpur, Ahmedabad, Gujarat (India) - 380015,

Sir,

With reference to your application No. GCT/CT04/FF/2024/46511 dated 22-Nov-2024, please find enclosed herewith the permission in Form CT-06 for conduct of **phase III** clinical trial titled **"A multicenter, randomized, double-blind, parallel, three-arm, active- and placebo-controlled therapeutic equivalence study for the comparison of clindamycin + tretinoin/Verisfield gel (1+0.025)% with Acnatac®/Meda gel [clindamycin + tretinoin (1+0.025)%] in the treatment of acne vulgaris" Protocol no. CLITRET/VER, Version 3.0 dated 11 July 2024 with a total of up-to 385 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

(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:

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:

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;

(vi) clinical trial shall be conducted in accordance with the approved clinical trial protocol and other

related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

(vii) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(viii) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;

(ix) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

(x) any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;

(xi) in case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

(xii) in case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

(xiii) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

(xiv) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;

(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) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

(xix) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &

Central Licencing Authority
Stamp

FORM CT-06

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

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

1. The Central Licensing Authority hereby permits **M/s Ethicare Clinical Trial Services (OPC) Pvt. Ltd, F-Block, 1101-1110, PNTC Building, Radio Mirchi Road, Vejalpur, Ahmedabad, Gujarat (India) - 380015** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. CLITRET/VER, Version 3.0 dated 11 July 2024** in the below mentioned clinical trial sites [As per Annexure].

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 _____

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Clindamycin+Tretinoin
Therapeutic class:	Lincosamide antibiotic and Retinoids
Dosage form:	Gels
Composition:	Clindamycin =10.0000 milligram (mg) Ph.Eur Active Tretinoin =0.2500 milligram (mg) Ph.Eur Active
Indications:	Acne Vulgaris

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Neo Skin Clinic, 1st Floor 102, Sai Ganesh Complex, Nearzaver nagar society, Waghodia Road, Vadodara, Gujarat 390019 Vadodara Gujarat -390019	Anand Institutional Ethics Committee, Anand Multispecialty Hospital, Vadodara, B Tower Sundarvan Complex, Beside IOCL Petrol Pump Near GorwaITI Vadodara, Gujarat -390016 India. ECR/725/Inst/GJ/2015/RR-21	Dr Kishan Ninama
2.	Government Medical College and Sir Sayaji rao General Hospital, SSGH, Ground floor, Department of Dermatology, Jail road, Indira Avenue, Sayajigunj, Vadodara-390001, Gujarat. Vadodara Gujarat -390001	Institutional Ethics Committee for human research medical college & SSG Hospital, Department of Pharmacology, 1st floor, Anandpura, Vadodara-390001, Gujarat, India. ECR/85/Inst/GJ/2013/RR-19	Dr Nipul Vara
3.	Renove Skin and Hair Clinic, 608, COPPERLEAF, Besides Utsav Elegance, Near Bhuyangdev Cross Roads, Ahmedabad Gujarat - 380061	Riddhi Medical Nursing Home IEC Riddhi Medical Nursing Home A/101 Jalaram Plaza Jawahar Chowk, Maninagar Ahmedabad Ahmedabad Gujarat -380008 India ECR/886/Inst/GJ/2016/RR-19	Dr Hardik Pitroda
4.	Smt. S.C.L Municipal Hospital, Saraspur, Smt. NHL Municipal Medical College V S Hospital Campus, Ellisbridge, Ahmedabad Ahmedabad Gujarat - 380006	Institutional Ethics Committee, NHLIEC, Smt. NHL Municipal Medical College V S Hospital Campus, Ellisbridge, Ahmedabad Ahmedabad Ahmedabad Gujarat – 380006 ECR/245/Inst/GJ/2013/RR-24	Dr Ashish Jagati
5.	Adorn Aesthetic Clinic, HOUSE of ADORN, opposite Reliance JIO Petrol pump, Ambawadi Circle, besides Shakuntal apartment, Ahmedabad Ahmedabad Gujarat - 380006	Mahavir Hospital Ethics Committee Mahavir hospitalff/e/101,102,103,104, 109, mahavir status near k. p heights m feet road , new Nikol, Ahmedabad Gujarat -382350 India ECR/1786/Inst/GJ/2023	Dr Pooja Desai
6.	JLN Hospital, JLN Hospital, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan 305001 India Ajmer Rajasthan - 305001	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan –305001 India ECR/1156/Inst/RJ/2018/RR-22	Dr Raj kumar Kothiwala

7.	Raja Rajeshwari Medical College and Hospital, 202, Mysore Rd, Kengeri Satellite Town, Kambipura, Karnataka 560074 Bengaluru Karnataka -560074	Institutional Ethics Committee Rajarajeswari Medical College and Hospital No. 202, Kambipura, Mysore Road, Bengaluru Karnataka. ECR/56/Inst/KA/2013/RR-24.	Dr Priya KS
8.	Rajalakshmi Hospital Research Center, Rajalakshmi Hospital Research Center Lakshmipura Main Road, Lake, opp. Lakshmipura, Lakshmipura, Vidyaranyapura, Bengaluru, Karnataka 560097 Bengaluru Karnataka - 560097	Rajalakshmi Hospital Institutional Ethics Committee, Rajalakshmi Hospital, 21/1, Lakshmi Pura, Main Road, Opp. Lakshmipura Lake, Vidyaranyapura Post, Bangalore, Urban Karnataka - 560097 India ECR/809/Inst/KA/2017/RR-20	Dr Savitha AS
9.	Medical College and hospital, Department of Dermatology, 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal 700073 Kolkata West Bengal	Institutional Ethics Committee for Human Research Medical College, Kolkata Medical College, Kolkata 88, College Street Kolkata Kolkata West Bengal -700073 India ECR/287/Inst/WB/2013/RR-19	Dr Rames Chandra Gorami
10.	Janta Hospital and maternity centre, OPD No. 1, Ground floor, Amra - Akhri Road, Bypass, Chunar Rd, near PaniTanki, Varanasi Uttar Pradesh- 221011	Janta Hospital Ethics Commitee Janta Hospital and Maternity Center Servey Number 374, Amara-Akhari Bypass, Chunar Road Varanasi Varanasi Uttar Pradesh –221011 ECR/839/Inst/UP/2016/RR-19	Dr Prachi Sharma
11.	Shree Pragati Foundations Hira Mongi Navneet Hospital,Valji Ladha Road, Near Kalidas, Natya Gruh, Mulund West, Mumbai-400080, Maharashtra, India Thane Maharashtra -40080	Hira Mongi Navneet Hospital Mulund West Mumbai Valaji Ladha Road Mumbai Mumbai City Maharashtra. ECR/1793/Inst/MH/2023	Dr Harsh Shah
12.	Gokul Hospital, 12,14 Malhar Plot, Near Virani Chowk, Vidhyanagar Main Road, Rajkot-360002, Gujarat-India Rajkot Gujarat - 360002	Institutional Ethics Committee Human Name and address of the Gokul Lifecare Private Limited, 12/14 Malhar Plot, Near Virani Chowk, Vidhyanagar Main Road, Rajkot-360002, Gujarat-India ECR/1469/Inst/GJ/2020	Dr Omdevsigh Gohel
13.	Mandya Institute of Medical Science, Mysuru Banglore Highway, Mandya-571403 Mandya Karnataka - 571403	Institution Ethics Committee, MIMS, Mandya Mandya Institute of Medical Sciences, Mandya MC Road Nehrunagar Mandya Mandya Karnataka -571401 India ECR/405/Inst/KA/2013/RR-21	Dr Shashikumar BM

14.	N.R.S Medical College and Hospital, 138, Acharya Jagdish Chandra Bose Rd, Sealdah, Raja Bazar, Kolkata, West Bengal 700014 Kolkata West Bengal - 700014	Ethics Committee, N.R.S. Medical College NRS Medical College And Hospital, NRS Medical College 138, A.J.C Bose Road Kolkata Kolkata West Bengal -700014 India. ECR/609/Inst/WB/2014/RR-20	Dr Kingshuk Chattergee
15.	Dr Arth Koshia Clinic, 201, JP 12th Business Hub, Surendra Mangaldas Rd, opp. Raj Stationers, Ambawadi, Ahmedabad, Gujarat 380015 Ahmedabad Gujarat - 380015	Riddhi Medical Nursing Home IEC Riddhi Medical Nursing Home A/101 Jalaram Plaza Jawahar Chowk, Maninagar Ahmedabad Ahmedabad Gujarat -380008 India ECR/886/Inst/GJ/2016/RR-19	Dr Arth Koshia

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