

F. No. ND/CT/24/000050
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002

To
M/s Om Sai Pharma Pack ,
Plot No. 38 & 39, Sector-11, I.I.E., SIDCUL (India) – 249403

Subject: Grant of permission to conduct Phase III Clinical Trial title ““A Multicentric, Randomized, Prospective, Active-Controlled, Parallel Group, Evaluator Blind, Comparative and Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Clascoterone Cream 1% w/w in Comparison with Adapalene Gel 0.1% w/w in the Treatment of Patients with Acne Vulgaris.” (Protocol no. CT/2024/04, protocol version-1.0, dated Sep 23, 2024) -regarding.

Reference: Letter Ref. No. ND/CT04/FF/2024/43891, Dated: 17-JUN-2024.

Sir,

With reference to your application no. ND/CT04/FF/2024/43891, Dated: 17-JUN-2024, please find enclosed herewith the permission in Form CT-06, No. **CT/ND/28/2024** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully,

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 of the New Drugs and Clinical Trials Rules, 2019;
- (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 the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 the Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of

- the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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 Licensing 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 Licensing 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.
 - (xix) The Informed Consent Document including ICF and Patient Information Sheet should clearly mention in understandable language about the details of the drug therapy that the patient may or may not receive.

FORM CT-06*(See rules 22, 25, 26, 29 and 30)***PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL
NEW DRUG****CT Permission No. CT/ND/28/2024**

The Central Licensing Authority hereby permits **M/s Om Sai Pharma Pack ,Plot No. 38 & 39, Sector-11, I.I.E., SIDCUL (India) - 249403 Telephone No.: 07088110202 FAX: 01146541382 E-Mail : REGULATORYOSPP@GMAIL.COM** to conduct Phase III clinical trial of the new drug **Clascoterone Cream 1% w/w** as per **Protocol no. CT/2024/04, protocol version-1.0, dated Sep 23, 2024** in the below mentioned clinical trial sites.

2. Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Clascoterone Cream 1% w/w
Therapeutic class:	Acne vulgaris
Dosage form:	Cream
Composition:	Clascoterone Cream 1% w/w contains Clascoterone 1.0% w/w Preservative: Benzyl Alcohol IP 1% w/w In a Cream Base Q.s.
Indications:	Indicated for the Topical Treatment of acne vulgaris inpatients 12 Year of age and older.

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/Registration Number
1.	Dr. Bindiya Barisal Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan.	Institutional Ethics Committee, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan. ECR/1222/Inst/RJ/2019/RR- 22
2.	Dr. Raj Kumar Kothiwala Department of Dermatology, Venereology and Leprosy, Jawahar Lal Nehru (J.L.N) Medical College, Kala Bagh, Ajmer- 305001, Rajasthan	Institutional Ethics Committee, Jawahar Lai Nehru Medical College, Kala Bagh, Ajmer- 305001, Rajasthan. ECR/1156/Inst/RJ/2018/RR- 22

3.	Dr. Dev Prakash Shivhare Department of Dermatology, LLR Hospital, GSVM Medical College, Swaroop Nagar, Kanpur-208002,Uttar Pradesh.	Ethics Committee, GSVM Medical College, Room No-125, 1 st Floor, Swaroop Nagar, Kanpur-208002, Uttar Pradesh. ECR/680/Inst/UP/2014/RR- 20
4.	Dr, Arvind Krishna Subharti Medical College and Hospital, Subharti Puram, NH-58, Delhi-Haridwar Bypass Road, Meerut-250005, Uttar Pradesh.	Institutional Ethics Committee, Subharti Medical College and Hospital, Subhartipuram, NH 58, Delhi-Haridwar Bypass Road, Meerut-250005., Uttar Pradesh, ECR/256/Inst/UP/2013/RR- 19
5.	Dr. Raja Bhattacharya Department of Medicine, Medical College and Hospital, Kolkata. MCH Building, 4 th Floor, 88 College Street, Kolkata-700073.	Institutional Ethics Committee for Human Research, Medical College and Hospital, Kolkata, 88, College Street, Kolkata-700073. ECR/287/Inst/WB/2013/RR- 19
6.	Dr. Saswati Haider Department of Dermatology, Calcutta School of Tropical Medicine, 108, Chinranjan Avenue, Calcutta-700073,West Bengal.	Clinical Research Ethics Committee, Department of Clinical and Experimental Pharmacology, Calcutta School of Tropical Medicine, 108, C R Avenue, Kolkata-700073. West Bengal. ECR/194/Inst/WB/2013/RR- 20
7.	Dr. Kingshuk Chatterjee Department of Dermatology, Nil Ratan Sarkar Medical College and Hospital, 138, Acharya Jagadish Chandra Bose Road, Kolkata-700014, West Bengal.	Ethics Committee, Nil Ratan Sarkar Medical College and Hospital, 138, Acharya Jagadish Chandra Bose Road, Sealdah, Raja Bazar, Kolkata-700014,West Bengal. ECR/609/Insti/WB/2014/RR- 20
8.	Dr. Kritika Goenka SMC Heart Institute and IVF Research Centre, Infront of BSNL Office, Vidhan Sabha Road, Khatnardi, Raipur-492007, Chhattisgarh.	SMC Heart Institute Institutional Ethics Committee, SMC Heart Institute and IF Research Centre, Infront of BSNL Office, Vidhan Sabha Road, Khamardih,Raipur-492007, Chhattisgarh.Vidhan Sabha Road, Khamardih, Raipur-492007, Chhattisgarh.

		ECR/1522/Inst/CG/2021
9.	<p>Dr. Vijay V. Raut</p> <p>Department of Dermatology. Rajarshee Chhatrapati Shau Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416012, Maharashtra.</p>	<p>Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College Institutional Ethics Committee 2 (RC SIVIGMCIEC2), Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital,</p> <p>Building No. 2, Quarter No. 3, Room No. 7, Dasara Chowk, Town Hall. Bhausingji Road. Kolhapur -416007, Maharashtra.</p> <p>ECR/703/Inst/MH/2015/RR-20</p>
10.	<p>Dr. Avdhut Bhalchandra Deshpande</p> <p>Prakash Institute of Medical Sciences & Research (PIMS&R), Urun-Islampur, Islampur-Sangali Road, Islampur, Tal-Walwa, Dist- Sangali-415409, Maharashtra.</p>	<p>Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Sciences & Research (PIMS&R), Urun-Islampur, Islampur-Sangali Road. Islampur, Tal-Walwa, Dist-Sangali-415409, Maharashtra.</p> <p>ECR/1052/Inst/MH/2018/RR-21</p>
11.	<p>Dr. Sunil Kumar Prabhu B</p> <p>Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oshalbag, Village-Dhargal, Tal-Pernem, Goa-403513.</p>	<p>Redkar Hospital Institutional Ethics Committee (RHIEC), Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Pernem, Goa-403513.</p> <p>ECR/902/Inst/GA/2018/RR- 21</p>
12.	<p>Dr. Gamit Hemangini Harishbhai</p> <p>Hope Well Medical Hospital, Block G, I' Floor, 101, 102. Sumel-8, Nr. Ajit Mill Char Rasta, Ralthiyal, Ahmedabad-380023, Gujarat.</p>	<p>Sangini Hospital Ethics Committee, C/o Sangini Hospital. First Floor, Santorini Square, Bill Abhishree Complex, Opp. Star Bazar Lane. Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat.</p> <p>ECR/147/Inst/GJ/2013/RR-19</p>

13.	Dr. Richa Gupta Aatman Hospital, 5, Anveshan Row House, Bopal Gain BRTS, Bopal-Ghuma Road, Bopal, Ahmedabad-380058, Gujarat.	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal-Ghuma Main Road, Bopal, Ahmedabad-380058, Gujarat. ECR/1565/Inst/GJ/2021
14.	Dr. Eswari L Department of Dermatology, Victoria Hospital, Bangalore Medical College & Research Institute (BMCRI), K R Road Fort, Benagaluru-560002, Karnataka.	Ethics Committee of BMCRI, Bangalore Medical College and Research Institute, Fort K R Road, Bengaluru (Bangalore) Urban-560002. Karnataka. E C R/302/Insti/KA/2013/RR-20
15.	Dr. Bangaru H Department of Dermatology. K R Hospital Mysore Medical College and Research Institute, Irwin Road, Mysore-570001. Karnataka.	Institutional Ethics Committee — Mysore Medical College and Research Institute and Associated Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysuru-570001, Karnataka. E C R/134/Inst/KA/2013/RR- 19
16.	Dr. Perumal M Panimalar Medical College Hospital & Research Institute, 1' Floor. Dermatology Department, Room No. 1, Varadharajapuram, Poonamallee, Chennai-600123, Tamil Nadu.	Panimalar Medical College Hospital & Research Institute -Institutional Ethics Committee (PMCHRIIHEC), Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai-600123, Tamil Nadu ECR/1399/Inst1TN/2020

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.

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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New Delhi