सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation (Headquarter)
Directorate General of Health Services
FDA Bhavan, ITO, Kotla Road
New Delhi -110002 (Delhi)
Phone No.: 91-11-23216367
E-Mail: dci@nic.in

File No: IND/CT/26/000033 Dated

To,

M/s Sun Pharma Advanced Research Company Limited,
Plot No. 5 & 6/1 Savli GIDC Estate, Manjusar Vadodara (India) – 391775
Telephone No.: 02667-666800 FAX: 02667-666800
E-Mail : SPARC.IRA@SPARCMAIL.COM

Subject: Application for grant of permission to conduct Phase Ib clinical trial entitled **"A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Efficacy and Safety of Topically Applied SPARC121 in Patients with Non-Segmental Vitiligo"** of new drug or investigational new drug as per protocol No.: SPARC121-25-01 Version 2.0 / Amendment 1 dated 29.05.2026- regarding.

Ref: Your Application No. IND/CT04/FF/2026/56482 dated 30.04.2026.

Sir,

With reference to your application No. IND/CT04/FF/2026/56482 dated 30.04.2026 please find enclosed herewith the permission in Form CT-06 to conduct subjected clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter 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 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;

(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 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 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 apply 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 utilized 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) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

(XIX) Clinical Study report (CSR) shall be submitted to this office after completion of the trial.

(XX) The firm shall intimate to CDSCO, if there is major dropout of subject from study.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.07.06 17:31:54 +05'30'

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

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

FORM CT-06

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

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

The Central Licensing Authority hereby permits M/s Sun Pharma Advanced Research Company Limited, Plot No. 5 & 6/1 Savli GIDC Estate, Manjusar Vadodara (India) – 391775 to conduct Phase Ib clinical trial entitled "**A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Efficacy and Safety of Topically Applied SPARC121 in Patients With Non-Segmental Vitiligo**" of the new drug or investigational new drug as per protocol No.: protocol No.: SPARC121-25-01Version 2.0/Amendment 1, dated 29.05.2026 in the below mentioned clinical trial sites.

2. Details of 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.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.07.06 17:32:33 +05'30'

Place: New Delhi
Date:

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Therapeutic class	Dosage form	Composition	Indications
SPARC121 Topical Foam 1%, 2%, 3%	Anti-inflammatory	Topical Foam	SPARC121= 1% In House Specification Active	For the treatment of Non-Segmental Vitiligo
SPARC121 Topical Foam 1%, 2%, 3%	Anti-inflammatory	Topical Foam	SPARC121= 2% In House Specification Active	For the treatment of Non-Segmental Vitiligo
SPARC121 Topical Foam 1%, 2%, 3%	Anti-inflammatory	Topical Foam	SPARC121= 3% In House Specification Active	For the treatment of Non-Segmental Vitiligo

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of Investigator
Department of Dermatology, Postgraduate Institute of Medical Education and Research, Chandigarh	Institutional Ethics Committee, Postgraduate Institute of Medical Education and Research, Chandigarh ECR/25/Inst /CH/2013/RR- 25	Dr. Davinder Parsad
All India Institute of Medical Sciences, New Delhi	Institutional Ethics Committee, All India Institute of Medical Sciences, New Delhi, Delhi ECR/538/Inst /DL/2014/RR -25	Dr. Somesh Gupta
Department of Dermatology, Nil Ratan Sircar Medical College and Hospital, Kolkata, West Bengal	Ethics Committee, N.R.S. Medical College, Kolkata, West Bengal ECR/609/Inst/WB/2014/RR-25	Dr. Kingshuk Chatterjee
Department of Dermatology, Mandya Institute of Medical Sciences, Mandya, Karnataka	Institutional Ethics Committee - MIMS, Mandya Institute of Medical Sciences, Mandya, Karnataka ECR/405/Inst/KA/2013/RR-21	Dr. Shashikumar B. M.
Department of Dermatology, Dr. R.N. Cooper General Hospital and HBT Medical College, Mumbai, Maharashtra	Institutional Ethics Committee, HBTMC and Dr. R.N Cooper General Hospital, Mumbai, Maharashtra ECR/1654/Inst/MH/2022	Dr. Smita Ghate

Department of Skin, Leprosy and STD, Victoria Hospital, Bangalore Medical College and Research Institute, Bengaluru, Karnataka	Ethics Committee of Bangalore Medical College and Research Institute, Bengaluru, Karnataka ECR/302/Inst/KA/2013/RR-25	Dr. Eswari. L
Department of Dermatology, Calcutta School of Tropical Medicine, Kolkata, West Bengal	Clinical Research Ethics Committee, School of Tropical Medicine, Kolkata, West Bengal ECR/194/Inst/WB/2013/RR-25	Dr. Saswati Halder
Department of Dermatology, LLR Hospital, GSVM Medical College, Kanpur, Uttar Pradesh	Ethics Committee GSVM Medical College, Kanpur, Uttar Pradesh ECR/680/Inst/UP/2014/RR-26	Dr. Yugal Rajput
Department of Dermatology, Lokmanya Tilak Municipal General Hospital and Lokmanya Tilak Municipal Medical College, Mumbai, Maharashtra	Institutional Ethics Committee Lokmanya Tilak, Mumbai, Maharashtra ECR/266/Lokmanya/Inst/MH/2013/RR-24	Dr. Rachita Dhurat
Department of Skin &V.D., S. P. Medical College & AG of Hospitals, Bikaner, Rajasthan	Ethics Committee, S.P. Medical College, Bikaner, Rajasthan ECR/27/SP/Inst/RJ/2013/RR-24	Dr. Rajesh Dutt Mehta
Department of Dermatology, GMERS Medical College & Civil Hospital, Ahmedabad, Gujarat	Institutional Ethics Committee, GMERS Medical College, Ahmedabad, Gujarat ECR/404/Inst/GJ/2013/RR -25	Dr. Krina Bharat Patel
Motilal Nehru Medical College associated with Swarooprani Nehru Hospital, Prayagraj, Uttar Pradesh	Institutional Ethics Committee, MLN Medical College Motilal Nehru Medical College, Prayagraj, Uttar Pradesh ECR/922/Inst/UP/2017/RR-22	Dr. Amit Shekhar
Department of Dermatology, Venereology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh	Institutional ethics Committee, Institute of Medical Sciences, Varanasi, Uttar Pradesh ECR/526/Inst/UP/2014/RR-20	Dr. Tulika Rai
Department of Dermatology (Skin& S.T.D), Mysore Medical College & Research Institute, Mysore, Karnataka	Institutional Ethics Committee, Mysore Medical College & Research Institute and Associated Hospitals, Mysore, Karnataka ECR/134/Inst/KA/2013/RR-24	Dr. Bisalvadi Lingaiah Nanjunda Swamy
B.J. Medical College and Civil Hospital, Ahmedabad, Gujarat	Institutional Ethics Committee, B.J. Medical College & Civil Hospital, Ahmedabad, Gujarat ECR/72/Inst/GJ/2013/RR-24	Dr. Surani Ashma Sirajbhai
Department of	KIMS Institutional Ethics Committee,	Dr. Nandini A S

Dermatology, Kempegowda Institute of Medical Sciences (KIMS Hospital), Bangalore, Karnataka	KIMS College, Bangalore, Karnataka ECR/216/Inst/Kar/2013/RR-2	
KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, Karnataka	Institutional Ethics Committee KLE University, Belagavi, Karnataka ECR/211/Inst/KA/2013/RR-24	Dr. Shivakumar Patil
CUTIS Academy of Cutaneous Sciences, Bengaluru, Karnataka	CUTIS Institutional Ethics Committee, Bengaluru, Karnataka ECR/930/Inst/KA/2017/RR-25	Dr. B.S. Chandrashekhar
Assured Care Plus Hospital, Nashik, Maharashtra	Institutional Ethics Committee, Assured Care Plus Hospital, Nashik, Maharashtra ECR/1756/Inst/MH/2022	Dr. Vartak Suneel Chandrakant
Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka	Institutional Ethics Committee, Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka ECR/56/Inst/KA/2013/RR-24	Dr. Hari Kishan Kumar Y
Department of Dermatology, Venereology and Leprosy, Mahatma Gandhi Medical College & Hospital, Jaipur, Rajasthan	Institutional Ethics Committee, Mahatma Gandhi Medical College & Hospital, Jaipur, Rajasthan ECR/125/Inst/RJ/2013/RR-24	Dr. Manisha Nijhawan
Cutis Institute of Dermatology, Srinagar, Jammu & Kashmir	Plus Medicare Hospitals Pvt. Ltd. Srinagar, Jammu & Kashmir ECR/2024/Inst/JK/2024	Dr. Wani Imran Majid
Apex Hospital Private Ltd., Jaipur, Rajasthan	Institutional Ethics Committee, Apex Hospital Private Ltd., Jaipur, Rajasthan ECR/380/Inst/RJ/2013/RR-24	Dr. Neetu Sidana
HCC Happiness Care and Cure Multispecialty Hospital LLP, Ahmedabad, Gujarat	Ethics Committee of Navneet Memorial Hospital, Navneet Memorial Hospital, Ahmedabad,Gujarat ECR/1866/Inst/GJ/2023	Dr. Doi Mo. Shadab M Rafik Ahmedbhai
Triveni Polyclinic, Nagpur, Maharashtra	Triveni Polyclinic Institutional Ethics Committee,Triveni Polyclinic, Nagpur, Maharashtra ECR/1402/Inst/MH/2020/RR-25	Dr. Ashutosh Mehata
Shubham Multispecialty Hospital, Ahmedabad, Gujarat	Shubham Institutional Ethics Committee, Shubham Multispecialty Hospital, Ahmedabad, Gujarat ECR/853/Inst/GJ/2016/RR-25	Dr. Jolapara Milap Babulal
Harmony Hospital, Ahmedabad Gujarat	IEC Momentous Mental Health and Rehabilitation Centre, Momentous Mental Health and Rehabilitation Centre, Gandhinagar, Gujarat	Dr. Hiren Pravinkumar Suthar

	ECR/2218/Inst/GJ/2026	
Shree Siddhivinayak Maternity and Nursing Home, Nashik, Maharashtra	Shree Siddhivinayak Hospital Ethics Committee, Shree Siddhivinayak Maternity and Nursing Home, Nashik, Maharashtra ECR/1247/Inst/MH/2019/RR-24	Dr. Kajale Nikhil Purushottam
Orchid Laser, Hair and Skin Clinic, Bhavnagar, Gujarat	Kiran Institutional Ethics Committee, Kiran Neuro - Psychiatry Care, Bhavnagar, Gujarat ECR/1826/Inst/GJ/2023	Dr. Parmar Kinal Nilesh kumar
Maharaja Agrasen Hospital, New Delhi, Delhi	Maharaja Agrasen Hospital Institutional Ethics Committee, Maharaja Agrasen Hospital, New Delhi, Delhi ECR/745/Inst/DL/2015/RR-21	Dr. Anjeeta Dhawan
Ojas Multispeciality Hospital, Pune, Maharashtra	Ojas Multi speciality Hospital Ethics Committee, Pune, Maharashtra ECR/1284/Inst/MH/2019/RR-24	Dr. Mamta Rajendra Patil
Saikrupa Hospital, Pune, Maharashtra	Saikrupa Hospital Institutional Ethics Committee, Saikrupa Hospital, Pune, Maharashtra ECR/1350/Inst/MH/2020/RR-25	Dr. Avinash Bajirao Jadhav
Manas Skin Clinic, Ahmedabad Gujarat	Riddhi Medical Nursing Home Institutional Ethics Committee, Ahmedabad, Gujarat ECR/886/INST/GJ/2016/RR·24	Dr. Patel Mitulkumar Ranchhodlal
Namostute Hospital, Gandhinagar, Gujarat	Institutional Ethics Committee Shashvat Surgicare Hospital, Gandhinagar, Gujarat ECR/1816/Inst/GJ/2023	Dr. Dhruv Ramanlal Patel
Anand Multispecialty Hospital & Research Centre Gandhinagar, Gujarat	Anand Ethics Committee, Anand Multispecialty Hospital & Research Centre, Gandhinagar,Gujarat ECR/1144/Inst/GJ/2018/RR-21	Dr. Kapadia Saurabh Dineshchandra
Department of Dermatology, Santosh Medical College and Hospital, Ghaziabad, Uttar Pradesh	Institutional Ethics Committee Sehgal Nursing Home Sehgal Nursing Home, New Delhi, Delhi ECR/1148/Inst/DL/2018/RR-21	Dr. Ram Chander
Neo Digital Skin Clinic, Himmatnagar, Gujarat	Keshav Psychiatric Hospital Institutional Ethics Committee, Keshav Psychiatric Hospital, Himmatnagar, Gujarat ECR/2029/Inst/GJ/2024	Dr. Shah Ruchir Hitendrabhai