

**F. No. ND/MA/25/000051**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**(New Drugs Division)**

FDA Bhawan, Kotla Road,  
New Delhi-11 0002

To

M/s Dr. Reddy's Laboratories Limited,  
IPDO, Survey No 54, Bachupally Village,  
Bachupally Mandal,  
Medchal - Malkajgiri District,  
Telangana (India) – 500090

**Subject: Application for grant of permission to conduct Phase-III Clinical Trial of Tapinarof cream 1% titled- "A randomized, multi-center, double-blind, parallel group, three-arm, placebo-controlled trial to evaluate the clinical equivalence of Tapinarof cream 1% of Dr Reddy's laboratories Ltd versus VTAMA ® (Tapinarof cream 1%, Dermavent Sciences Inc.) using the clinical endpoint in patients with plaque psoriasis (Protocol no. DRL-IND-NDA30-TAP/2024, Protocol Version no. 3.0 dated 17.04.2025)-regarding.**

Sir,

With reference to your application no. ND/CT21/FF/2025/48655 dated 25.12.2024, please find enclosed herewith the permission in **Form CT-06, vide Permission No. CT/ND/23/2025** 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  
RAGHUVANSHI  
**(Dr. Rajeev Singh Raghuvanshi)**  
**Drugs Controller General (India)**

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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 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;
- (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 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 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 the 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 authorized 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 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 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) 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/23/2025**

The Central Licensing Authority hereby permits **M/s Dr. Reddys Laboratories Limited, IPDO, Survey No 54, Bachupally Village, Bachupally Mandal, Medchal - Malkajgiri District, Telangana (India) – 500090 Telephone No.: 04044346000 FAX: 04044346125 E-Mail: MADHAVIK@DRREDDYS.COM** to conduct Phase III Clinical Trial of the new drug as per **DRL-IND-NDA30-TAP/2024, version 3.0 dated 17.04.2025** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:

<b>Names of the new drug or investigational new drug:</b>	<b>Tapinarof cream 1%</b>
<b>Therapeutic class:</b>	<b>Aryl hydrocarbon receptor modulating agent</b>
<b>Dosage form:</b>	Cream
<b>Composition:</b>	Each gram of Cream contains: Tapinarof.....10 mg Cream base..... qs
<b>Indications:</b>	It is indicated for the topical treatment of plaque psoriasis in adults.

**Details of Clinical trial sites -**

<b>Sr. No.</b>	<b>Name of Principal Investigator &amp; Trial Sites</b>	<b>Ethics Committee Name/Registration Number</b>
1	Dr. Manjunath Shenoy M  Omega Hospital, Mahaveer Circle, Kankanady, Mangalore Hyderabad Telangana - 500090	Omega Ethical Committee Omega Hospital Omega Hospital Mahaveer Circle, Kankanady Mangalore Dakshina Kannada Karnataka – 575002 India <b>EC Registration No.</b> ECR/89/Inst/KA/2013/RR-20
2	Dr. Saswati Halder  Calcutta School of Tropical Medicine, 108, Chittranjan Avenue Calcutta Medical College, college square, Kolkata West Bengal, India	Clinical Research Ethics Committee, School of Tropical Medicine, Kolkata School Of Tropical Medicine 108, Chitta Ranjan Avenue, Kolkata - 700073 Kolkata Kolkata WestBengal - 700073 India <b>EC Registration No.</b> ECR/194/Inst/WB/2013/RR-20

3	<p>Dr. Chetan Lalseta</p> <p>Shree Giriraj Multispeciality Hospital, 150 Feet ring road, 27, Navjyot park Main road, Rajkot-360005, Gujarat, India</p>	<p>B.T Savani Kidney Hospital Ethics Committee B.T. Savani Kidney Hospital, Near university Gate, University Road, Rajkot- 360005, Gujarat, India</p> <p><b>EC Registration No.</b> ECR/1936/Inst/GJ/2024</p>
4	<p>Dr. Ghanshyam Vinod</p> <p>Jupiter Hospital &amp; research Center, Opp. ICAI Bhavan, Sunpharma Atladara road, vadodara - 390012, Gujarat, India</p>	<p>Jupiter Hospital &amp; Research Center Institutional Ethics Committee Jupiter Hospital and Research Centre, Opp. ICAI Bhavan, Sunpharma Atladara Road, Vadodara- 390012, Gujarat, India</p> <p><b>EC Registration No.</b> ECR/1894/Inst/GJ/2023</p>
5	<p>Dr. Kinjal Mistry</p> <p>Kkasturi Medicare Pvt. Ltd. Harshniketan, Gaondevi Road, Behind Navrang Hotel, Bhayandar West, Dist-Thane, Maharashtra, India-401101</p>	<p>Shah Lifeline Hospital And Heart Institute, Ethics Committee, Geeta Nagar, Phase 7, Near Flyover Bridge, Mira Bhayandar Road, Mira Road (East), Dist-Thane, Maharashtra, India-401105</p> <p><b>EC Registration No.</b> ECR/1588/INST/MH/2021</p>
6	<p>Dr. Ruchir Shah</p> <p>NEO Digital Skin Clinic 3rd Floor, Gurukrupa Complex, Near Mehta Petrol pump, Girdhar Nagar, Himatnagar, Gujarat-383001</p>	<p>Keshav Psychiatric Hospital Institutional Ethics Committee Keshav Psychiatric Hospital, First Floor, Gurukrupa Complex, Girdharnagar, Himmatnagar, Sabarkantha, Gujarat - 383001</p> <p><b>EC Registration No.</b> ECR/2029/Inst/GJ/2024</p>
7	<p>Dr. Anshul Warman</p> <p>Aartham Multi Super Speciality Hospital Aartham Multi Super Speciality Hospital, Opp, Government Polytechnic College, near Panjarapole, Cross road, L Colony, Ambawadi, Ahmedabad, Gujrat- 380006</p>	<p>Aartham Ethics Committee Aartham Hospitals LLP, Opp. Polytechnic, Near Panjarapole Cross Road, Ambawadi, Ahmedabad Gujarat - 380015 India</p> <p><b>EC Registration No.</b> ECR/1520/Inst/GJ/2021</p>
8	<p>Dr. Sakshi Midha</p> <p>Excelcare Hospital, 103 Sanjay Nagar A, Joshi Marg, Kalwar Road, Jhotwara, Jaipur-302012- Rajasthan</p>	<p>Institutional Ethics Committee sardarmal Khandaka Memorial Hospital Sardarmal Khandaka Memorial Hospital, Kalwar Road Hatoj Jaipur Rajasthan - 302012 India</p> <p><b>EC Registration No.</b> ECR/1032/Inst/RJ/2018/RR-21</p>

9	Dr. Stuti Mahajan  Raneshwar Multispeciality Hospital A-4 Parshaw Nagar Society, Vasna Road, Before vasna, Ravi park society, Saiyed Vasna, Vadodara- 390015	IRB Raneshwar Multispeciality Hospital A4- Parshaw Nagar society Vasna Road, Ravi Park Society, Saiyed Vasna, Vadodara- Gujarat-390015 <b>EC Registration No.</b> ECR/1232/Inst/GJ/2019/RR-24
10	Dr. Kishan Ninama  Dhiraj Hospital Dhiraj Hospital-SBKS MI & RC Sumandeep Vidyapeeth Deemed to be University, At & Po Piparia, Ta Waghodia, Dist Vadodara-391760, Gujarat, India	Institutional Ethics Committee SV, Sumandeep Vidyapeeth Sumandeep Vidyapeeth At and Post Pipariya, Pipariya Vadodara Gujarat - 391760 India <b>EC Registration No.</b> ECR/152/Inst/GJ/2013/RR-24
11	Dr. Godse Kiran Vasant  Dr. D Y Patil Medical College, Hospital & Research Center Sector-5, Nerul, Navi Mumbai- 400706, Maharashtra, India	Institutional Ethics Committee D Y Patil Medical College, Sector-5, Nerul, Navi Mumbai-400706, Thane, Maharashtra, India <b>EC Registration No.</b> ECR/195/Inst/MH/2013/RR-19
12	Dr. Monika Gowda  Medstar Speciality Hospital #641/17/1/3, Kodigehalli Main road, Sahakarnagar, Bangalore-560092, Karnataka, India	Medstar Speciality Hospital Ethics Committee, #641/17/1/3, Kodigehalli Main road, Sahakarnagar, Bangalore-560092, Karnataka, India <b>EC Registration No.</b> ECR/1324/Inst/2019/RR-24
13	Dr. Wani Imran Majid  Cutis Institute of Dermatology Cutis Institute of Dermatology, Hyderpora, Shrinagar-190014, J & K	Plus Medicare Hospitals Pvt Ltd Durganag, Dalgate Bridge, Munshi Bagh, Srinagar, Jammu & Kashmir-190001 <b>EC Registration No.</b> ECR/2024/Inst/JK/2024
14	Dr. Rajkumar Kothiwala  Jawahar Lal Nehru Medical College Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001	Institutional Ethics Committee Jawahar Lal Nehru Medical College, kala bagh, Ajmer-305001, Rajeshthan India <b>EC Registration No.</b> ECR/1156/Inst/RJ/2018/RR-22
15	Dr. Mamta Patil  Ojas Multispeciality Hospital, Sr no 203/1, Bhondave Chock, D.Y Patil College Road, Ravet, Pune- 412101	Ojas Multispeciality Hospital Ethics Committee, Sr no 203/1, Bhondave Chock, D.Y Patil College Road, Ravet, Pune- 412101 <b>EC Registration No.</b> ECR/ 1284/Inst/MH/2019/RR-24
16	Dr. Ambuj Singh  Medica Hospital, Chunar Road, Amara Village, Awleshpur, Varanasi-221108 UP	Ethics Committee of Sai Medicity PVT LTD, B-33/33-52, Rohit nagar, Near Nariya Varanasi,221005 UP <b>EC Registration No.</b> ECR/1660/Inst/UP/2022
17	Dr. Gitesh Sawatkar  AIIMS Department of Dermatology,	Institutional Ethics Committee for clinical trial, 3rd floor, Department of Pharmacology medical building, AIIMS, PlotN0 2, sector 20, Mihan, sumthana,

	Venerology and leprology, plot no.2, Sector- 20, MIHAN, Sumthana, Dahegaon, Nagpur-4411	Dahegaon, Nagpur-441108  <b>EC Registration No.</b> ECR/1392/Inst/MH/2020
18	Dr. Kranti Chandan  Department of Skin VD, Indira Gandhi Institute of medical Sciences(IGIMS), Sheikhpura, Patna, Bihar- 800014 India	Institutional Ethics Committee, Indira Gandhi Institute of medical Sciences, sheikhpura, patna, Bihar, 801014  <b>EC Registration No.</b> ECR/640/Inst/BR/2014/RR-20
19	Dr. Megha Pandey  Gyandeep Medicare Hospital Samne Ghat, Lanka Varanasi UP- 221005	Ethics Committee of Sai Medicity PVT LTD Ethics Committee of Sai Medicity PVT LTD, B33/33-52, Rohit Nagar, Naria, Varansi, Uttar Pradesh-221005, India  <b>EC Registration No.</b> ECR/1660/Inst/UP/2022
20	Dr. Sonal Shendkar  Lifepoint Multispeciality hospital Clinical Research Department , 3rd floor, 145/1, Mumbai- Bangalore Highway, Near Highway, Near Hotel sayaji , Wakad, Pune- 411075	Lifepoint Research Ethics Committee 3rd floor, Clinical Research department, 145/1, Mumbai-Bangalore Highway, Near Highway, Near Hotel sayaji, Wakad, Pune- 411075  <b>EC Registration No.</b> ECR/751/Inst/MH/2015/RR-21
21	Dr. Zafar Abbas Chaudhary  Shree Krishna Medicare Hospital and ICU 9/617, Ground Floor, Mehul Park, B/H GD Modi College, Jampura Anandnagar Hwy, Palanpur, Banaskantha, Gujarat-385001, India	Krishna Ethics Committee 9/617, Mehul Park, Ground Floor, B/H G D Modi college, Jampura Anand nagar Highway, Palanpur, Banaskantha, Gujarat- 385001  <b>EC Registration No.</b> ECR/2053/Inst/GJ/2025
22	Dr. Hital Patel  DHS Multispeciality Hospital Vastrapur Lake, Himalaya Mall Link Road, Sunrise Park, Vastrapur, Ahmedabad-380054	Sangini Hospital Ethics Committee First Floor, Santorini Square, B/H Abhishree Complex, Opp. Starbazar, Nr. Jodhpur Cross Road, Satelite, Ahmedabad- 380015 <b>EC Registration No.</b> ECR/147/Inst/GJ/2013/RR-24
23	Dr. Bhavik Bhavsar  Lavanya Skin Clinic and Laser Centre, 303, Aishwarya Complex, Opp. Shell Petrol Pump, Jawahar Chawk, Maninagar, Ahmedabad,380008	Netaji Polyclinic Institutional Ethics Committee Netaji Polyclinic, Block No. 50, Room No. 1180, 81, 88, Last Bus Stop, Meghaninagar, Ahmedabad, Gujarat- 380008, India <b>EC Registration No.</b> ECR/1870/Inst/GJ/2023
24	Dr. Adarsh Gowda  Santosh Hospital, 6/1, Promenade	Santosh Hospital Institutional Ethics Committee Santosh Hospital, 6/1,

	Road, Behind Colse Park, Bengaluru-560005	Promenade Road, Behind Colse Park, Bengaluru-560005 <b>EC Registration No.</b> ECR/1062/Inst/KA/2018/R-21
29	Dr. Nandita Patel  Kiran Hospital Multi super speciality Hospital and Research centre Nr. Sumul Dairy, Surat, Gujarat- 395004, India	Kiran Hospital Ethics Committee, Kiran Hospital Multi super speciality Hospital and Research centre, Nr. Sumul Dairy, Surat, Gujarat-395004, India  <b>EC Registration No.</b> ECR/1029/Inst/GJ/2018/RR-21
30	Dr. Neetu Sidana  Apex Hospital Pvt. Ltd. S P 4 and 6, Malviya Industrial Area, Malviya Nagar, Jaipur- 302017, Rajasthan, India	Institutional Ethics Committee Apex Hospital Pvt. Ltd., S P 4 and 6, Malviya Industrial Area, Malviya Nagar, Jaipur-302017, Rajasthan, India, <b>EC Registration No.</b> ECR/380/Inst/RJ/2013/RR-24
31	Dr. Shivkumar Patil  KLES Dr. Prabhakar Kore Hospital and MRC Nehru Nagar, Belagavi-590010, Karnataka, India	Institutional Ethics committee, KLE academy of Higher Education and Research (KAHER) JNMC Campus, Nehru Nagar, Belagavi- 590010, Karnataka, India. <b>EC Registration No.</b> ECR/211/Inst/KA/2013/RR-24
32	Dr. Sonam Singh  Dr. Sachan's Skin, Hair and Cosmetic Clinic, 129/E Opp Archis School, Shyam Nagar, Kanpur- 208013, India	Ethics Committee Atmaram Child Care and Critical Care, 53/128 Y Block, Naubasta, Kanpur-208011, India.  <b>EC Registration No.</b> ECR/1925/Inst/UP/2024
33	Dr. Vaibhav Kalambe  Asian Institute of Medical Sciences P/72, Milap Nagar, MIDC, Dombivli (E), Maharashtra, India-421203	Suraksha Ethics Committee Asian Institute of Medical Sciences, P/72, Milap Nagar, MIDC, Dombivli (E), Maharashtra, India-421203  <b>EC Registration No.</b> ECR/644/Inst/MH/2014/RR-20
34	Dr. Shivani Bansal  All India Institute of Medical Sciences Bathinda, Mandi Dabwali Road, Jodhpur Romana, Punjab, India-151001	Institutional Ethics Committee AIIMS Bathinda, All India Institute of Medical Sciences Bathinda, Mandi Dabwali Road, Jodhpur Romana, Punjab, India-151001 <b>EC Registration No.</b> ECR/1466/Inst/PB/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** Digitally signed by RAJEEV  
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**(Dr. Rajeev Singh Raghuvanshi)**  
**Central Licensing Authority**

**New Delhi**