



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  
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**File No. CT/24/000080**

To,

M/s Parexel International Clinical Research Private Limited,  
CoWrks, RMZ Eco world, Ground Floor, Bay Area –Adjacent to Building 6A,  
Outer Ring Road, Devarabeesanahalli Village, BENGALURU, INDIA -560103

Sir,

With reference to your application No. GCT/CT04/FF/2024/43526 dated 12/06/2024, please find enclosed herewith the permission in Form CT-06 for conduct of **Phase III** clinical trial titled, “**A randomized, double-blind, placebo-controlled, parallel-group study to assess the efficacy, safety, and tolerability of dexpropionolone administered orally for 52 weeks in participants with severe eosinophilic asthma (EXHALE-3)**” Protocol No.: AR-DEX-22-02 Version No. India Specific Amendment 1 Protocol Date 17-Sep-2024 with a total of up-to 50 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:-

- 1) Human biological samples i.e. Human blood (whole), serum, plasma and urine related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
- 2) 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;
- 3) 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;
- 4) 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;
- 5) 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;
- 6) 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;
- 7) 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;
  - 8) 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;
  - 9) 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;
  - 10) 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;
  - 11) 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;
  - 12) 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;
  - 13) 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;
  - 14) 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;
  - 15) 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;
  - 16) 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
  - 17) 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;
  - 18) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
  - 19) 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;
  - 20) 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,

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India) &  
Central Licensing 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. Parexel International Clinical Research Private Limited, CoWrks, RMZ Eco world, Ground Floor, Bay Area –Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, BENGALURU, INDIA - 560103 Telephone No.: 8067723000 FAX: 80 67723001 E-Mail : PAREXELINDIA@PAREXEL.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: AR-DEX-22-02 Version No. India Specific Amendment 1 Protocol Date 17-Sep-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 \_\_\_\_\_

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

**Annexure:**

Details of new drug or investigational new drug:

<b>Names of the new drug or investigational new drug</b>	Dexpramipexole dihydrochloride monohydrate
	Dexpramipexole dihydrochloride monohydrate
<b>Therapeutic class:</b>	Small molecule eosinophillowering agent
	Small molecule eosinophillowering agent
<b>Dosage form:</b>	Tablets
	Tablets
<b>Composition:</b>	Dexpramipexole (KNS-760704)=75.0000 milligram (mg) In House Specification Active
	Dexpramipexole (KNS-760704)=150.0000 milligram (mg) In House Specification Active
<b>Indications:</b>	Severe eosinophilic asthma
	Severe eosinophilic asthma

**Annexure:**

Details of clinical trial site:

<b>S.No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	G B Vaghani Multispeciality Hospital, 75-80, Ishwarkrupa soc., Opp. Maharana Pratap Udhyan, Varachha Main Rd, Chowpatty, Surat, 395006, Gujarat, India	Global Ethics Committee, Global Hospital, Global Point 4rth floor, Beside Navjivan Restaurant, Sarthana Jakatnaka, Surat, Gujarat, 395006, Gujarat, India  Institutional (ECR/850/Inst/GJ/2016/RR-20)	Dr. Chandrakant Balabhai Ghevariya
2.	4th Floor Department of Respiratory Medicine, Critical Care and Sleep Medicine Super Speciality Hospital, Government Medical College Hospital, Tukdoji Square, Nagpur- 440003, Maharashtra, India	Institutional Ethics Committee Department of Pharmacology, Government Medical College and Hospital, Nagpur, Maharashtra, Medical Square, Hanuman Nagar Nagpur- 440003  Institutional ECR/43/Inst/MH/2013/RR-19	Dr. Sushant Meshram
3.	Anand Surgical Hospital Pvt Ltd, Memco Cross Road, Naroda Road, Naroda, Ahmedabad-382345, Gujarat	Anand Surgical Hospital IEC, Anand Surgical Hospital Pvt Ltd, Memco Cross Road, Naroda Road, Naroda, Ahmedabad-382345, Gujarat  Institutional ECR/798/Inst/GJ/2016/RR-21	Dr. Nisarg Mahendra kumar Patel

4.	104-TB & Chest Department, GMERS Medical college and Civil Hospital, Sola Gram Rd, Beside High Court, Ahmedabad-380060, Gujarat (India)	Institutional Ethics Committee GMERS Medical college Sola, GMERS Medical College & Civil Hospital Sola Highway , Beside Gujarat High Court, Ahmedabad – 380061, Gujarat (India)  Institutional ECR/404/Inst/GJ/2013/RR-20	Dr. Kirankumar C Rami
5.	Harmony Hospital 301, Pushkar Icon , Nr. Shukan Cross Road , Nikol- Naroda Rd Above Croma , New India Colony , Nikol, Ahmedabad, Gujarat 382350 Sabarkantha, Gujarat (India)	IEC Shashavat Surgicare Hospital , Shashvat Surgicare Hospital Plot No. 3,4 ,4th Floor Room No.401 , Shyam Residency Kudasan, Gandhinagar, Gujarat, India, 382421  Institutional ECR/1816/Inst/GJ/2023	Dr. Pradip kumar Hiraji Damor
6.	J.K. Orthopedic Hospital, behind mehta petrol Pump, Near S.T. Stand, Girdharnagar, Himmatnagar-383001,	J.K. Orthopaedic Hospital Ethic Committee, J.K. Orthopaedic Hospital 3rd floor, Behind Mehta Petrol Pump, Near S.T. Stand, Girdharnagar, Himmatnagar-383001, Sabarkantha, Gujarat (India)  Institutional ECR/1697/Inst/GJ/2022	Dr Mitul Chaudhari
7.	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg Sector-7, Vidyadhar Nagar Jaipur Rajasthan -302039	IEC, Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg Sector-7, Vidyadhar Nagar Jaipur Rajasthan -302039 India  Institutional ECR/1222/Inst/RJ/2019/RR-22	Dr Manish Kumar
8.	Respira Chest And Critical Care, 5 <sup>th</sup> Floor, Plot No.5, Shree Radheya Health Heights Central Bazar Road, Ramdaspath, Nagpur Maharashtra - 440010 India	Respira Institutional Ethics Committee Respira Chest & Critical Care 5th Floor, Plot no.5, Shree Radhey Health Heights, Central Bazar Road, Ramdaspath, Nagpur, Maharashtra 440010, India  Institutional ECR/1848/Inst/MH/2023	Dr. Vinit Niranjane

9.	Dept. of PCCM PGIMS, PGIMS Rohtak Haryana - 124001	Institutional Ethics Committee Director Office Illrd floor, PGIMS Rohtak, Haryana, 124001  Institutional ECR/29/Inst/HR/2013/RR-19	Dr Pawan Kumar Singh
10.	Lifepoint Multispeciality, Hospital, 145/1, Mumbai- Banglore Highway, Near Hotel Sayaji, Wakad Pune Maharashtra - 411057	LPR Ethics Committee, Lifepoint Multispeciality Hospital,145/1, Mumbai- Banglore Highway, Near Hotel Sayaji, Wakad,Pune-411057, Maharashtra, India  Institutional ECR/751/INST/MH/2015/RR-21	Dr Sarpe Dnyandeep Bhojaraj
11.	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer- 305001, Rajasthan, India	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan  Institutional ECR/1156/Inst/RJ/2018/RR-22	Dr. Piyush Arora
12.	Ishwar Institute of Health Care, Ishwar Heights, 1 <sup>st</sup> floor, plot no 7, gut no 6/1, beside Punjabi bhavan, Padegaon, Aurangabad - 431002, Maharashtra, India.	Ethics Committee of Ishwar Institute of Health Care, Ishwar Heights, 3rd floor, plot no 7, gut no 6/1, beside Punjabi bhavan, Padegaon, Aurangabad - 431002, Maharashtra, India.  Institutional ECR/988/Inst/MH/2017/RR-20	Dr. Bardapurkar Shreehas Suhas
13.	Department of Medicine, SSG Hospital, Medical College- Baroda Jail Road, Indian Avenue, Vadodara, Gujarat, 390001	Institutional Ethic Committee for Human Research Medical College Baroda, Anandpura, Vadodara Gujarat-390001, India  Institutional ECR/85/Inst/GJ/2013/RR-24	Dr. Keyur Madan Brahme
14.	Murarilal Chest Hospital, GSVM Medical College, Swaroop Nagar, Kanpur- 208002, UP, India	Ethics Committee GSVM Medical College, Principal Office, GSVM Medical College, Kanpur-208002, UP, India  Independent ECR/1222/Inst/RJ/2019/RR-22	Dr. Sanjay Kumar Verma

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