NIL

File No. FDC/MA/24/000097
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.:011-23236965
Fax No. :011-23236973

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 22-Oct-2025

To,

M/s. Zydus Healthcare Limited.,
Bhagey Khola, NH No. 10, Majhitar,
Rangpo, Sikkim- 737136

Subject: **Permission to conduct Phase III clinical trial with the FDC of Diphenhydramine Hydrochloride and Phenylephrine Hydrochloride Syrup (12.5mg + 5mg)/5ml (Vide protocol no. CT/2025/15, Version no. 01, dated 05.08.2025)- regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 30.03.2024 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-46/2025** under the provision of Drugs and Cosmetics Act and Rules. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully,
RAJEEV SINGH RAGHUVANSHI
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Date: 2025.10.22 17:38:56 +05'30'
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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:
    i. 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:
    ii. 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. The formulation intended to be used in the clinical trial study shall be manufactured under GMP conditions using validated procedures.

XIX. It may kindly be noted that merely granting permission to conduct Clinical trials/Bioavailability or Bioequivalence study with the drug does not convey or imply that, based on the Clinical trial data/ Bioavailability or Bioequivalence study data generated with the drug, permission to market this drug in the country will automatically be granted to you.

FORM CT-06

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

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

Permission no.: FDC-CT-06-46/2025

1. The Central Licencing Authority herebypermits **M/s. Zydus Healthcare Limited., Bhagey Khola, NH No. 10, Majhitar, Rangpo, Sikkim - 737136, Tel No. `9733004842, Fax No: 03592246187, Email: sumanbag@zyduslife.com** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(CT/2025/15, version no. 01, dated 05.08.2025)** in the below mentioned clinical trial sites.

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.

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Place: New Delhi **Central Licencing Authority**

Date: 22-Oct-2025

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Diphenhydramine Hydrochloride and Phenylephrine Hydrochloride Syrup (12.5mg + 5mg)/5ml
Therapeutic class:	Anti-histamine and nasal decongestant
Dosage form:	Syrup
Composition:	Each 5ml contains: Diphenhydramine Hydrochloride IP ….. 12.5mg Phenylephrine Hydrochloride IP 5mg
Indications:	It is indicated for the symptomatic relief of cough and upper respiratory symptoms, including nasal congestion, associated with common cold and allergic rhinitis.

Details of clinical trial site:

Names and address of clinical trial site:	As per annexure- A
Ethics committee details:	As per annexure- A
Name of principal investigator:	As per annexure- A

Annexure-A

Permission no.: FDC-CT-06-46/2025

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1.	Dr. Prabhat Kumar Sharma	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. Veer Bahadur Singh	Department of Medicine Sardar Patel Medical College and A.G. Hospitals, Sardar Patel Colony, Bikaner-334001, Rajasthan.	Institutional Ethics Committee, S.P. Medical College, Pawanpuri, Bikaner- 334003, Rajasthan. **ECR/27/SP/Inst/RJ/2013/RR-24**
3.	Dr. Amit Kumar Asati	SMC Heart Institute and IVF Research Centre, Infront of BSNL Office, Vidhan Sabha Road, Khamardih, Raipur-492007, Chhattisgarh.	SMC Heart Institute Institutional Ethics Committee, SMC Heart Institute and IVF Research Centre, Infront of BSNL Office, Vidhan Sabha Road, Khamardih, Raipur-492007, Chhattisgarh. **ECR/1522/Inst/CG/2021**
4.	Dr. Shubhra Kanti Sen	Department of ENT, 2nd Floor, Baker Ward, Nil Ratan Sircar 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/Inst/WB/2014/RR-25**
5.	Dr. Diptak Bhowmick	Life Line Diagnostic Centre cum Nursing Home, 4A, Wood Street, Kolkata- 700016, West Bengal	Institutional Ethics Committee, Life Line Diagnostic Centre cum Nursing Home, 4A, Wood Street, Kolkata- 700016, West Bengal. **ECR/1334/Inst/WB/2020**
6.	Dr. Raja Bhattacharya	Department of Medicine, Medical College and Hospital, MCH Building, 2nd Floor, 88 College Street, Kolkata-700073, West Bengal.	Institutional Ethics Committee for Human Research, Medical College and Hospital, 88 College Street, Kolkata-700073, West Bengal. **ECR/287/Inst/WB/2013/RR-24**
7.	Dr. Sagar Vivek Redkar	Redkar Hosptial and Research Centre, Mumbai-Goa Highway, Oxelbag, Village- Dhargal, Tal-Pernem, Goa-403513	Redkar Hosptial Institutional Ethics Committee (RHIEC), Redkar Hosptial and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Pernem, North Goa-403513, Goa. **ECR/902/Inst/GA/2018/RR-21**
8.	Dr. Vijay Kumar Barge	Department of Medicine, Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General	Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College Institutional Ethics Committee 2 (RCSMGMCIEC2), Rajarshee Chhatrapati Shahu Maharaj Govt.

		Hospital Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416012, Maharashtra.	Medical College Chhatrapati Pramila Raje General Hospital, Building No. 2, Quarter No. 3, Room No. 7, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416007, Maharashtra. **ECR/703/Inst/MH/2015/RR-20**
9.	Dr. Vijay Kumar Shivajirao Patil	Prakash Institute of Medical Sciences & Research (PIMS&R), Urun- Islampur, Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali- 415409, Maharashtra.	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Sciences & Research (PIMS&R), Urun- Islampur, Islampur- Sangali Road, Islampur, Tal Walwa, Dist, Salgali- 415409, Maharashtra. **ECR/1052/Inst/MH/2018-21**
10.	Dr. Ansari Rizwanahmed Nurulhasan	Hope Well Medical Hospital Block G, 1st Floor, 101, 102, Sumel-8, Nr. Ajit Mill Char Rasta, Rakhiyal, Ahmedabad-380023, Gujarat.	Sangini Hospital Ethics Committee C/o Sangini Hospital, First Floor, Santorini Square, B/H Abhishree Complex, Opp, Star Bazar lane, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad- 380015, Gujarat. **ECR/147/Inst/GJ/2013/RR-24**
11.	Dr. Bammidi Nageswara Rao	Department of ENT, Government ENT Hospital, Andhra Medical College Pedda Waltair Visakhapatnam-530017, Andhra Pradesh	Institutional Ethics Committee, King George Hospital, Maharanipeta, Collector Office Junction, Visakhapatnam-530002, Andhra Pradesh, **ECR/197/Inst/KGH/2013/RR-20**
12.	Dr. Konatham Rambabu	Department of General Medicine, Visakha Institute of Medical Sciences, NH- 16, Hanumanthavaka Junction, Visakhapatnam- 530040, Andhra Pradesh	Institutional Ethics Committee, Visakha Institute of Medical Sciences (VIMS), S. No. 97/2, Hanumanthavaka Chinagadilli Village, Visakhapatnam- 530040, **ECR/1421/Inst/AP/2020**
13.	Dr. Murali Krishna M	In Patient Block, 3rd Floor, Department of General Medicine Gandhi Hospital, Musheerabad, Secunderabad-500003, Telangana.	Institutional Ethics Committee, Gandhi Medical College and Hospital, Musheerabad, Secunderabad-500003, Telangana. **ECR/180/Inst/AP/2013/RR-24**

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Central Licencing Authority

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