

F. No. ND/MA/25/000033
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
Torrent Pharmaceuticals Limited (Research centre),
Village –Bhat, Dis: Gandhinagar - 382428,
Gujarat, India

Subject: Application for grant of permission to conduct Phase-III study of Resmetirom Tablets 60mg, 80mg & 100mg titled- “A Randomized, Multi-Centric, Single Blind, Double Dummy, Active-Controlled, Parallel Group, Phase III Clinical Trial to Evaluate the Efficacy and Safety of Resmetirom Oral Tablets in Adult Subjects with Non-alcoholic Steatohepatitis” Protocol no. CT/RESM/NASH/2025/3_1, Version no.: 3, Dated: 02-04-2025 - regarding.

Sir,

With reference to your application no. **ND/MA/25/000033** dated **10-Mar-2025**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/11/2025** 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 Digitally signed by RAJEEV
RAGHUVANSHI SINGH RAGHUVANSHI
Date: 2025.06.18 10:16:10
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(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:

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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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.

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/11/2025**

The Central Licensing Authority hereby permits **M/s. Torrent Pharmaceuticals Limited (Research centre), Village –Bhat, Dis: Gandhinagar - 382428, Gujarat, India Telephone No.: 91-079-26585090 FAX: 91-079-26582100 E-Mail: SUSANABY@TORRENTPHARMA.COM** to conduct Clinical Trial of the New Drug as per Protocol Number: **CT/RESM/NASH/2025/3_1, Version no.: 3, Dated: 02-04-2025** in the below mentioned clinical trials sites.

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

Names of the new drug or investigational new drug:	Resmetirom Tablets 60mg, 80mg & 100mg
Therapeutic class:	Thyroid hormone receptor-beta (THR-beta) agonist
Dosage form:	Tablets
Composition:	<p>Resmetirom Tablets 60 mg Each film coated tablet contains: Resmetirom.....60mg Excipients.....q.s. Color: Titanium Dioxide I.P</p> <p>Resmetirom Tablets 80 mg Each film coated tablet contains: Resmetirom.....80mg Excipients.....q.s. Colors: Titanium Dioxide I.P. and Yellow Oxide of Iron</p> <p>Resmetirom Tablets 100 mg Each film coated tablet contains: Resmetirom.....100mg Excipients.....q.s. Colors: Titanium Dioxide I.P., Yellow Oxide of Iron and Red Oxide of Iron</p>
Indications:	For the treatment of adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in conjunction with diet and exercise.
Details of clinical trial sites-	
Sr. No.	Name of Principal Investigator & Trial Sites
Ethics Committee Name/ Registration Number	
1.	Dr. Deepak Bansal (Gastroenterologist)
	EC, Vincare Hospital, Vincare Hospital, 100 Feet Road Opp, Petrol Pump Bathinda,

	Vincare Hospital, 100, Feet Road, Bathinda-151001, Punjab, India	Punjab-151001 India ECR/1657/Inst/PB/2022
2	Dr. Manoj Kumar (Assistant Professor) Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan –305001 India	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan–305001 India ECR/1156/Inst/RJ/2018/RR-22
3	Dr. Shyam Sunder Sharma (Professor) Manglam Plus Medicity Hospital, Sector 05, Shipra Path, Mansarovar Jaipur Rajasthan – 302020 India	IEC Manglam Medicity Hospital, Manglam Plus Medicity Hospital Sector 5, Shipra Path, Mansarovar Jaipur Rajasthan –302020, India ECR/1643/Inst/RJ/ 2022
4	Dr. Tanmay Sunil Kumar Vyas (Gastroenterologist) Ahmedabad Gastro and Liver Hospital, Bock-A, 501 to 508, Aaryan Workspaces - 3, Besides Mahatma Gandhi Labour Institute, Drive In Rd, opp. Manav Mandir, Memnagar, Ahmedabad, Gujarat 380052, India	Institutional Ethics Committee Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir Bopal-Ghuma Main Road, Bopal Ahmedabad Gujarat –380058, India ECR/1565/Inst/GJ/2021
5	Dr. Vatsal Kirit Kumar Mehta (Gastroenterologist) Alfa Gastro and Liver Care, 2nd floor, dream square complex, Opp. Ramdev peerji Maharaj Mandir, Nr Nirnay Nagar underbridge, Akhbar Nagar, Ahmedabad Gujarat -380081, India	Institutional Ethics Committee Aatman Hospital, 5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal-Ghuma Main Road, Bopal Ahmedabad Gujarat –380058 India ECR/1565/Inst/GJ/2021
6	Dr. Varadaraj Gokak (Gastroenterologist) Arihant Hospital, A Unit of Dixit Health Care, C Square, CTS No. 10632/A1/B Nagar, Belgaum Belagavi Karnataka – 590010,India	Institutional Ethics Committee Arihant Hospital, Arihant Hospital, A Unit of Dixit Health Care C Square, CTS No. 10632/A1/B Nehru Nagar, Belgaum Belagavi Karnataka –590010, India ECR/1840/Inst/KA/2023
7	Dr. Abhishek Yadav (Gastroenterologist) Subharti Medical College and Hospital Subhartipuram NH-58, Delhi-Haridwar Bypass Road, Meerut, Uttar Pradesh –250005, India	Institutional Ethics Committee, Subharti Medical College and Hospital, Subhartipuram NH-58, Delhi-Haridwar Bypass Road, Meerut Uttar Pradesh - 250005 India. ECR/256/Inst/UP/2013/RR-24
8	Dr. Prashant Katiyar (Gastroenterologist) Atharva Multi speciality Hospital and Research Centre H- 4/Comm-2, Construction Div-21. UP Avas Vikas Parishad, Sector-E, Lucknow- 226003, Uttar Pradesh, India	Institutional Ethics Committee, Atharva Multi speciality Hospital and Research Centre, H-4/Comm-2, Construction Div -21, UP Avas Vikas Parishad, Sector E, Lucknow, Uttar Pradesh - 226003 India ECR/1241/Inst/UP/2019/RR-24
9	Dr. Ashok Rohidas Mohite (Gastroenterologist) GI-One Hospital Amrut Sai Solitair, Besides Goldies Cinema, Railway Station Road. Aurangabad- 431005, Maharashtra, India.	Ethics Committee Ajanta Superspeciality Hospital, Ajanta Superspeciality Hospital Plot No 15, N-13/C, HUDCO Corner Beside Yash Hotel Ajanta Road Aurangabad - 431003, Maharashtra ECR/1499/Inst/MH/2021

10	Dr. Souveek Mitra (Hepatologist) Centre for clinical research - John C. Martin Centre for Liver research and innovations (CCRJCMLRI), Indian Institute of liver and digestive sciences (IILDS) Campus, Sitala East, Sonarpur, South 24 PGS, Kolkata-700150, West Bengal.	Human Research Ethics Committee, Indian Institute Of Liver And Digestive Sciences (IILDS), Sitala East, Malipukuria Jagadishpur Sonarpur, South 24 Parganas – 700150, West Bengal ECR/1568/Inst/WB/2021
11	Dr. Abhinav Gupta (Gastroenterologist) Marudhar Hospital, A-93-99, Singh Bhoomi Khatipura Road Jaipur - 302012 Rajasthan India.	Marudhar Hospital Ethics Committee, Marudhar Hospital A-93-99, Singh Bhoomi Khatipura Road Jaipur - 302012 Rajasthan, India ECR/586/Inst/RJ/2014/RR-20

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