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# F. No. ND/CT/25/000129
# 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 Gufic Biosciences Limited,**
**Subhash Road-A Block, Vile Parle East Mumbai,**
**Maharashtra, India, Maharashtra (India) – 400057**

**Subject: Grant of permission to conduct Phase-IV Clinical trial of drug Dalbavancin Hydrochloride for injection 500mg vide protocol titled "Multicenter, Prospective, Non-Comparative, Non-Randomized, Open Label, Phase IV clinical trial to evaluate the safety and efficacy of Dalbavancin in patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSIs) (Protocol Number: CRS/25/007, Version No: 1.0, Amendment 1 dated 06 May 2026)" regarding.**

Sir,

With reference to your application no. **ND/CT04/FF/2025/53582 dated 29.12.2025,** please find enclosed herewith the permission in **Form CT-06 vide no. CT/ND /23/2026** 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
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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 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.

**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/23/2026**

The Central Licensing Authority hereby permits, **M/s Gufic Biosciences Limited, 37, 1st Floor, Kamla Bhavan, II Swami Nityanad Road, ANDHERI EAST MUMBAI (India) - 400069 Telephone No.: 022-67261000 FAX: 022-67261067 E-Mail : NVSFDA@GUFICBIO.COM** to conduct clinical trial of the new drug as per **Protocol Number: CRS/25/007, Version No: 1.0, Amendment 1 dated 06 May 2026** 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:~~** | | **Dalbavancin Hydrochloride for injection 500mg** |
| **Therapeutic class:** | | Antibacterial |
| **Dosage form:** | | Lyophilized Powder for solution for injection |
| **Composition:** | | Each vial contains:<br>Dalbavancin Hydrochloride equivalent to Dalbavancin ……500mg. |
| **Indications:** | | Dalbavancin for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI), caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin susceptible and methicillin resistant strains), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (including S. anginosus, S. intermedius, S. constellatus) and Enterococcus faecalis (vancomycin susceptible strains) |
| **Details of clinical trial sites-** | | |
| **Sr. No.** | **Name of Principal Investigator & Trial Sites** | **Ethics Committee Name/ Registration Number** |
| 1. | **Dr.Madhumita Das,**<br>College of Medicine & Sagore Dutta, Hospital, 578, B.T. Road, Kamarhati, Kolkata-700058, West Bengal. | The Institutional Ethics Committee, College of Medicine & Sagore Dutta Hospital, Office of Principal, 578 B.T Road, Kamarhati Kolkata, 700058, West Bengal.<br>**ECR/1210/Inst/WB/2019/RR-22** |
| 2 | **Dr. Kingshuk Chatterjee,** | Ethics Committee N.R.S. Medical C |

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|---|---|---|
| | N.R.S. Medical College and Hospital, 138, Acharya Jagdish Chandra Bose Rd, Sealdah, Raja Bazar, Kolkata - 700014, West Bengal. | ollege and hospital, Acharya Jagdish Chandra Bose Rd, Sealdah, Raja Bazar, Kolkata - 700014, West Bengal.<br>**ECR/609/Inst/WB/2014/RR-25** |
| 3 | **Dr. Chandrashekhar Mahakalkar,**<br>Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha - 442107, Maharashtra | Institutional Ethics Committee of DMIHER, Datta Meghe Institute Of Higher Education And Research, Sawangi (Meghe), Wardha- 442107 Maharashtra.<br>**ECR/440/Inst/MH/2013/RR-24** |
| 4 | **Dr. Prashant Rahate,**<br>Rahate Surgical Hospital, Dept of surgery, Kolbaswami Chowk, Near Telephone Exchange Square, Old Mangalwari, Central Avenue, Nagpur - 440008, Maharashtra | Ethics Committee, Rahate Surgical Hospital, Rahate Surgical Hospital, 517, Kolba Swami Square, Old Mangalwari, Central Avenue Road, Nagpur - 440008, Maharashtra.<br>**ECR/601/Inst/MH/2014/RR-25** |
| 5 | **Dr. Ashok Ninan Oommen,**<br>Jubilee Mission Medical College & Research Institute P.B. No. 737, Jubilee Mission P.O.. Thrissur -680005, Kerala. | Institutional ethics committee, Jubilee mission medical college and research institute, Bishop Alappat Road, Thrissur-680005, Kerala.<br>**ECR/835/Inst/KL/2016/RR-24** |
| 6 | **Dr. Vijay Kumar Sonkar,**<br>S.N. Medical College Moti Katra, Mantola, Agra - 282003, Uttar Pradesh. | Institutional Ethics Committee S.N Medical College &S.N Medical College Raja Mandi, Near Agra College Agra central library, Moti Katra, Mantola, Agra - 282003, Uttar Pradesh.<br>**ECR/1409/Inst/UP/2020/RR-2025** |
| 7. | **Dr. Raj. S,**<br>Mahatma Gandhi Medical College & Research Institute, No. 45, Pondy - Cuddalore ECR Main Road, Pillaiyarkuppam-607402, Puducherry. | Institutional Human Ethics Committee (IHEC), First Floor, College Block, Mahatma Gandhi Medical College & Research Institute, No. 45, Pondy - Cuddalore ECR Main Road, Pillaiyarkuppam-607402, Puducherry.<br>**ECR/451/Inst/PO/2013/RR-24** |
| 8. | **Dr. Samir Kumar Patel,**<br>KIMS Hospital, Kushabhadra Campus, KIIT Campus-5, Patia, Bhubaneswar, Khordha-751024, Odisha | Institutional Ethics Committee Kalinga Institute of Medical Sciences, Kushabhadra Campus (Campus-5), KIIT Campus-5, Patia, Bhubaneswar, Khordha-751024, Odisha.<br>**ECR/321/Inst/OR/2013/RR-25** |
| 9. | **Dr Prathvi Shetty,**<br>Father Muller Research centre. Indoor Stadium Complex, Father Muller Campus, Father Muller Road Kankanady Mangaluru -575002, Karnataka | Father Muller Institutional Ethics Committee, Father Muller Medical College, Father Muller Road, Kankanady Mangaluru -575002, Karnataka.<br>**ECR/540/Inst/KA/2024/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 RAGHUVANSHI

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**(Dr. Rajeev Singh Raghuvanshi)**
**Central Licensing Authority**
**Stamp**

**New Delhi**