File No. SND/MA/21/000056
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
23 JUL 2021

To,

M/s. Macleods Pharmaceuticals Ltd.,
Atlanta Arcade, 3rd Floor, Church Road,
Near Leela Hotel, Andheri-Kurla Road,
Andheri (East), Mumbai – 400059.

Subject: "Permission to conduct Phase III Clinical trial of Amikacin Sulphate Gel 5 % w/w "Title – A Prospective, Multi-center, Randomized, Open-label, Parallel-group, Comparative Study to Evaluate the Clinical Efficacy and Safety of Amikacin sulphate 5% w/w Gel versus Mupirocin 2% w/w Ointment in Treatment of Subjects with Venous Ulcer. (Protocol No. CT-017-AMIK-2020, Version Number: 1.0, Date:-25-02-2021) - Reg.

CT NOC No.: CT/SND/102/2021

Sir,

With reference to your Application No. SND/CT21/FF/2020/21513 dated 26.02.2021 please find enclosed herewith the permission in Form CT-06, CT NOC No. CT/SND/102/2021 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,

(Dr. V. G. Somani)
Central Licensing Authority

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 case be responsible for the study at the trial site or the centre, as the case 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 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 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 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) 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) Submit a copy of the Ethics Committee approval letter for all the site.

(xx) EGFR instead of Serum creatinine should be included in concentration in exclusion criteria.

(xxi) All venous ulcer patients should be included. In the culture sensitivity, if found resistant, those patient may be droped out.

(xxii) Serum concentration should be measured twice during the course of study.

FORM CT-06

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

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

CT NOC NO.: CT/SND/102/2021

The Central Licensing Authority hereby permits **M/s Macleods Pharmaceuticals Ltd., Atlanta Arcade, 3rd Floor, Church Road, Near Leela Hotel, Andheri-Kurla Road, Andheri (East), Mumbai – 400059** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. CT-017-AMIK-2020, Version Number: 1.0, Date:-25-02-2021** in the below mentioned clinical trial sites.

2. Details of new drug or investigational new drug:

Names of the new drug:	Amikacin Sulphate Gel 5% w/w
Therapeutic class:	Antibacterial
Dosage form:	Gel
Composition:	Each gram of gel contains: Amikacin sulfate IP equivalent to Amikacin 5% w/w Preservative: Methyl Paraben IP.02% w/w Propyl Paraben IP .....0.02% w/w
Indications:	1. Skin infected trauma, skin and mucosa erosions, pyodermias and other similar conditions due to Pseudomonas or other bacteria that are sensitive to Amikacin. 2. Stasis ulcers or ischemic ulcers (due to artery disease, hypertension or diabetes), where the product should be administered with caution in cases where tab results indicated that the ulcer is infected by sensitive in Amikacin bacteria.

Details of clinical trial sites

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/Registration Number
1	Dr. Jayesh shah, Hi-Tech Multispeciality Hospital, Plot No. 1180, Sector 3/D, Gh11/2, Bus Stand, Gandhinagar Gujarat – 382003, India.	Hi-Tech Multispeciality Hospital, Ethics Committee, Hi-Tech Multispeciality Hospital. ECR/1057/Inst/GJ/2018/RR-21
2	Dr. Apporv Dineshkumar Singh, Crescent Hospital and Heart Centre, Plot No. 25, Behind Old Mount Carmel School, Near Lokmat Square, Dhantoli, Nagpur- 440012, Maharashtra, India.	Institutional Ethics Committee, Crescent Hospital and Heart Centre. ECR/682/Inst/MH/2014/RR-21
3	Dr. Dnyaneshwar Halnor, Vijay Vallabh Hospital and Medical Research Centre, Plot No. 423, Tirupati Nagar Phase-I, Bolinj, Virar (West), Palghar, Maharashtra – 401303, India.	Institutional Ethics Committee, Vijay Vallabh Hospital and Medical Research Centre. ECR/880/Inst/MH/2017/RR-20

4	Dr. Harbade Suresh Rangnathrao, Ishwar Institute of Health care Ishwar heights, Plot no. 7, Gut No. 8/1, Besides Punjabi Bhavan, Mumbai Nashik Highway Road, Padegaon-Aurangabad – 431002, Maharashtra.	Ethics Committee of Ishwar Institute of Health care Ishwar heights ECR/988/Inst/MH/2017/RR-20
5	Dr. Prem Prakash, Indira Gandhi Institute of Medical Sciences, Department of General Surgery, 4th floor, Ward Block, Sheikhpura, Patna-800014, Bihar	Institutional Ethics Committee, Indira Gandhi Institute of Medical Sciences ECR/640/Inst/BR/2014/RR-20
6	Dr. Arpit Panchal,Rhythm Heart Institute, Department of Surgery, Near Siddharth Bunglows, Samasavi Road, Vadodara – 390022, Gujarat, India	Rhythm Heart Institute Ethics Committee, ECR/224/Inst/GJ/2013/RR-19
7	Dr. Brij Mohan, Brij Medical Centre Pvt. Ltd., 94-E, Panki, Near Panki Police Station, Kanpur-208020, Uttar Pradesh, India	Ethics Committee Brij Medical Centre ECR/642/Inst/UP/2014/RR-20
8	Dr. Shendkar Sonal Mahadev, Lifepoint Multispeciality Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune – 411057, Maharashtra	LPR Ethics Committee, Lifepoint Multispeciality Hospital, ECR/751/Inst/MH/2015/RR-18

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.

(Dr. V. G. Somani)
Central Licensing Authority
Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road
New Delhi-1100

New Delhi
Date: 12 JUL 2021