



File No. BIO/CT/24/000116

Dated: 15-01-2025

To,
M/s Shilpa Biologicals Private Limited,
Plot No. 532-A Belur Industrial Area
Dharwad, Karnataka (India) – 580011

Subject: Application for grant of permission to conduct Phase III clinical trial entitled – “A Phase III, Double Blind, Parallel, Active Controlled Efficacy, Safety and Immunogenicity Assessment Study of Recombinant Human Serum Albumin 20% in Decompensated Liver Cirrhosis Patients with Ascites or Edema” as per Protocol No. NAL/SBPL/P3/2024, Version 1 dated 16-Sep-2024- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/45583 dated 23.09.2024 -reg

Sir,

With reference to your application No BIO/CT04/FF/2024/45583 dated 23.09.2024, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(I) CSR shall be submitted to this office after completion of trial.

- (II) 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 Licensing Authority under rule 8
- (III) 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;
- (IV) 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;
- (V) The Central Licensing 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;
- (VI) 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.
- (VII) 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.

- (VIII) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (IX) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal.
- (X) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination.
- (XI) 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 Licensing 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.
- (XII) 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter.
- (XIII) 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter.
- (XIV) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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.
- (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 Licensing 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) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

RAJEEV SINGH
RAGHUVANSHI

Yours faithfully,

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

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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FORM CT-06

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

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

The Central Licensing Authority hereby permits M/s Shilpa Biologicals Private Limited, Plot No. 532-A Belur Industrial Area, Dharwad, Karnataka (India) – 580011 to conduct Phase III clinical trial titled- “A Phase III, Double Blind, Parallel, Active Controlled Efficacy, Safety and Immunogenicity Assessment Study of Recombinant Human Serum Albumin 20% in Decompensated Liver Cirrhosis Patients with Ascites or Edema” as per Protocol No. NAL/SBPL/P3/2024, Version 1 dated 16-Sep-2024 in the below mentioned clinical trial sites.

2. Details of 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.
4. It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Place: New Delhi
Date: 15.01.2025

CDSCO

RAJEEV SINGH
RAGHUVANSHI

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

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सत्यमेव जयते

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Recombinant Human Albumin 20% (r-DNA origin) solution for infusion		
Therapeutic class	Plasma substitutes and plasma protein fractions		
Dosage form:	Solution for Infusion Presented as 20% albumin at pH 7.0+/- 0.3 as drug product in 50 mL and 100 mL fill volumes in type II glass vial.		
Composition:	Each 100mL contains-		
	Name of Ingredients	Function	Quantity in g/100mL
	Recombinant Human Albumin (In-house)	Active substance	20
	Sodium Caprylate (Multi-Pharmacopeial)	Stabilizer	266 +25 mg
	Sodium Chloride (Multi-Pharmacopeial)	Stabilizer	819 +117 mg
Water for Injections (Multi-Pharmacopeial)	Vehicle	q.s.	
Indications:	Decompensated Liver Cirrhosis Patients with Ascites or Edema		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Max Super Specialty Hospital (A unit of Max Healthcare Institute Limited) FC 50 C & D Block, Shalimar Bagh, New Delhi 110088	Max Healthcare Ethics Committee, Ground Floor, Office of Ethics Committee, West Block, Near MS office Max Super Specialty Hospital, Saket (A unit of Max Healthcare Institute Limited) 1, Press enclave Road, Saket, New Delhi 110017 EC reg no. ECR/118/Inst/DL/2013/RR-19	Dr Piyush Gupta
2.	NRS Medical College & Hospital, 138 AJC Bose Road, Kolkata 700014, West Bengal India	Ethics Committee NRS Medical College, NRS Medical College and Hospital, 138 AJC Bose Road, Kolkata 700014, West Bengal, India EC Reg No. ECR/609/Inst/WB/2014/RR-20	Dr. Pinaki Roy
3.	Nuha Hospitals Dr No 12-19-61/62, Old Bank Road Kothapet, Guntur, Andhra Pradesh 522001, India	Institutional Ethics committee of Nuha Hospitals, Nuha Hospitals Dr No 12 -19-61/62, Old Bank Road Kothapet, Guntur, Andhra Pradesh 52200	Dr Shaik Nagoor Basha

		EC Reg No ECR/1593/Inst/AP/2021	
4.	KIMS-Kingsway Hospital, SPANV Medisearch Lifescience Private Limited, 44, Parwana Bhawan, Kingsway, Nagpur 440001, Maharashtra, India	Kingsway Hospitals Ethics Committee, Kingsway Hospitals, 44, Parwana Bhawan, Kingsway, Nagpur, Maharashtra-440001, India EC Reg No ECR/1269/Inst/MH/2019 EC/RENEW/INST/2024/17770	Dr Samir Surendra Patil

