



Government of India
Central Drugs Standard Control Organisation(Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/20/000088

Dated: 14-Dec-2022

To,

M/s Lazuline Biotech Private Limited,
Plot No. 34 A, Huda Heights, Near Lotus Pond,
Road No. 12, Banjara Hills Hyderabad (India) – 500034

Subject: Application for grant of permission to conduct Phase I clinical trial entitled –"An Open Label, Randomized, Four Dose, Parallel, Safety, Tolerability, Immunogenicity Assessment Study of Recombinant Human Albumin Followed by Pharmacokinetic Comparison with Plasma Derived Human Serum Albumin in Healthy Adults" as per Protocol No.: rHA/LZBPL/PHASE I/2022 Version No. 3.0 Dated 30 Sep 2022- regarding

Ref.: Your Application No. BIO/CT04/FF/2020/20469 dated 02-Jul-2020

Sir,

With reference to your Application No.: BIO/CT04/FF/2020/20469dated 02-Jul-2020, 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). **Interim results of Part I of the study shall be submitted for review before initiation of Part 2 of the study;**
- (ii). **Firm shall submit undertaking by Principal Investigator as per Table 4 of Third Schedule of New Drugs & Clinical Trial Rules, 2019;**
- (iii). **Phase I clinical trial batches shall be manufactured using standardized procedures under GMP condition which demonstrate consistency of the manufacturing process after obtaining permission of manufacturing for clinical trial batches in Form CT-11;**
- (iv). **The batch size shall be such that it can be simulated for further clinical trials;**
- (v). **The firm shall submit ongoing stability data generated from the clinical trial batch which should cover the duration of clinical trial and shall inform this office, if there is any failure or out of specifications observed in ongoing stability study;**
- (vi). 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;
- (vii). 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;
- (viii). 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;

FORM CT-06

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

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

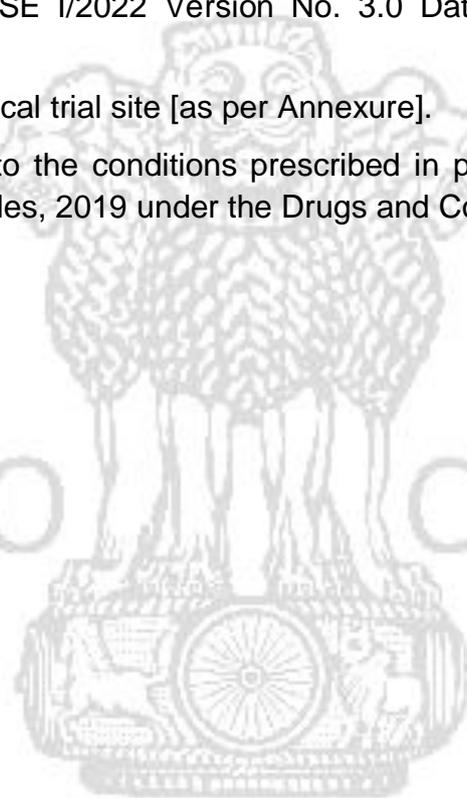
The Central Licencing Authority hereby permits M/s Lazuline Biotech Private Limited, Plot No. 34 A, Huda Heights, Near Lotus Pond, Road No. 12, Banjara Hills Hyderabad (India) – 500034 to conduct clinical trial of the new drug or investigational new drug study titled "**An Open Label, Randomized, Four Dose, Parallel, Safety, Tolerability, Immunogenicity Assessment Study of Recombinant Human Albumin Followed by Pharmacokinetic Comparison with Plasma Derived Human Serum Albumin in Healthy Adults**" as per Protocol No.: rHA/LZBPL/PHASE I/2022 Version No. 3.0 Dated 30 Sep 2022 in the below mentioned clinical trial site.

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.

Place: New Delhi
Date: 14-Dec-2022

**VENUGO
PAL G
SOMANI (Soman)**
Drugs Controller General (India)

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=DRUGS
CONTROLLER GENERAL (INDIA),
pseudonym=112046a34e21727ba255748
732c456d249073e50e953d9e5b58748ee31
13e, postalCode=110002, st=DELHI,
serialNumber=e97241aa0c0bba41522525ff
e8079272b64957e652b455c8b1c202adeaf
56



सत्यमेव जयते

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

Names of the new drug or investigational new drug:	Human Albumin (r-DNA origin)																		
Therapeutic class:	Blood products and Plasma substitutes																		
Dosage form:	Solution for Infusion in 100 mL vial																		
Composition:	<table border="1"> <thead> <tr> <th>Sr. No.</th> <th>Ingredients</th> <th>Reference to Quality Standard</th> <th>Quantity (mg / mL)</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Human Albumin (r-DNA Origin)</td> <td>In-house</td> <td>200</td> </tr> <tr> <td>2.</td> <td>Sodium Caprylate</td> <td>In House</td> <td>0.00665</td> </tr> <tr> <td>3.</td> <td>Water for injection</td> <td>I.P./U.S.P./Ph. Eur./B.P.</td> <td>Q.S. to 1 mL</td> </tr> </tbody> </table>			Sr. No.	Ingredients	Reference to Quality Standard	Quantity (mg / mL)	1.	Human Albumin (r-DNA Origin)	In-house	200	2.	Sodium Caprylate	In House	0.00665	3.	Water for injection	I.P./U.S.P./Ph. Eur./B.P.	Q.S. to 1 mL
Sr. No.	Ingredients	Reference to Quality Standard	Quantity (mg / mL)																
1.	Human Albumin (r-DNA Origin)	In-house	200																
2.	Sodium Caprylate	In House	0.00665																
3.	Water for injection	I.P./U.S.P./Ph. Eur./B.P.	Q.S. to 1 mL																
Indications:	<p>In the treatment of Liver Cirrhosis with signs of signs and symptoms of hypovolemia and hypoalbuminemia in:</p> <ul style="list-style-type: none"> • Early hepatic decompensation (serum albumin levels- <2.8g/dl with or without ascites) who may or may not require paracentesis (Abdominal Tap) • Spontaneous bacterial peritonitis 																		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	M/s SRM Medical College Hospital & Research Centre, SRM Nagar, Kattankulathur, Chengalpattu-603 203, Tamil Nadu, India	Institution Ethics Committee, SRM Medical College Hospital and Research Centre, SRM Nagar, Potheri, Kattankulathur - 603203, Kanchipuram District. EC Reg. No.: ECR/431/Inst/TN/2013/RR-19	Dr. Satyajit Mohapatra, MD (Pharmacology)