File No: BIO/CT/21/000148
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

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 Dr. Anil K of M/s Syngene International Limited, Clinical Development Tower-1 Semicon Park, Electronic City, Phase-II, Hosur Road Bangalore (India)-560100 Telephone No.: null FAX: null E-Mail: ANIL.DR@SYNGENEINTL.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol no.: VXA-COV2-102, Version no. 2.00, Dated 25-FEB-2022 in the below mentioned clinical trial sites.

CT No.: CT- 20/2022

2. Details of new drug or investigational 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 vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

VENUGOPAL G SOMANI

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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: 12-SEP-2022

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Adenoviral-Vector Based Vaccine (VXA-CoV2-1.1-S) (Enteric Coated Tablet)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Enteric Coated Tablet (vaccine)</td></tr>
<tr><td>Composition:</td><td>Each dose of 276mg Enteric coated tablet contains:
<table>
<tr><th>Name of Active ingredient</th><th>Quantity</th></tr>
<tr><td>Adenoviral-Vector Based Vaccine (VXA-CoV2-1.1-S)</td><td>$5x10^9$ to $1.7x10^{10}$ IU</td></tr>
<tr><td>Tromethamine</td><td>1.1 mg</td></tr>
<tr><td>Sucrose</td><td>5.7 mg</td></tr>
<tr><td>Arginine</td><td>5.7 mg</td></tr>
<tr><td>Povidone K90</td><td>5.7 mg</td></tr>
<tr><td>Fish Gelatin Hydrolysate</td><td>5.7 mg</td></tr>
<tr><td>Hydrochloric acid</td><td>1.1 mg</td></tr>
<tr><td>Microcrystalline Cellulose</td><td>167.1 mg</td></tr>
<tr><td>Pre-gelatinized starch 1500</td><td>55.7 mg</td></tr>
<tr><td>Magnesium Stearate</td><td>1.1 mg</td></tr>
<tr><td>Colloidal Silica, hydrophobic</td><td>1.1 mg</td></tr>
<tr><td>Copovidone (Kollidon VA-64)</td><td>5.1 mg</td></tr>
<tr><td>Methyl Methacrylate copolymer, Type A (Eudragit L100)</td><td>13.9 mg</td></tr>
<tr><td>Triethyl citrate</td><td>3.5 mg</td></tr>
<tr><td>Talc</td><td>3.5 mg</td></tr>
</table></td></tr>
<tr><td>Indications:</td><td>Prevention of Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)</td></tr>
</table>

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Human Pharmacology Unit, Syngene International Limited, Clinical Development, Tower I, Semicon Park, Electronic City, PhaseII, Hosur Road, Bangalore560 100, India	Institutional Ethics Committee, Sri Venkateshwara Hospitals Ethics Committee, Sri Venkateshwara Hospitals, #27, 29th Main Road, Rashtra Kuvempu Nagara BTM 2nd Stage, BTM Layout, Bangalore-560076, Karnataka, India. [EC Registration no.: ECR/298/Inst/KA/2013/RR19]	Dr. Siddangouda Patil

In addition to point 4, the permission is subject to following conditions:

I. The clinical trial should be conducted as per approved protocol titled “A Phase 1b Open-Label, Randomized, Dose-Ranging Trial to Determine the Safety and Immunogenicity of an Adenoviral-Vector Based Vaccine (VXA-CoV2-1.1-S) Expressing a SARS-CoV-2 S Protein and dsRNA Adjuvant Administered Orally to Healthy Human Adult Volunteers.” [Protocol no.: VXA-COV2-102, Version no. 2.00, Dated 25-FEB-2022].

II. Firm is requested to submit the revised Affidavit declaring that the information about study drug as mentioned in Investigators Brochure is correct and based on available facts.

III. The firm is requested to submit the detail of analytical procedures and reports for bioburden, Mycoplasma, Residual DNA, In-vitro Assay, Host cell protein, identity, Adenovirus immunoassay, viral particle appearance.
IV. DSMB shall be constituted for assessment of safety of the clinical trial.
V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOPAL
G SOMANI

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