File No: BIO/CT/22/000085
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 of M/s IQVIA RDS (India) Private Limited, Omega Embassy TechSquare, Marathahalli-Sarjapur, Outer Ring Road Kadubeesanahalli Bangalore (India)- 560103, Telephone No.: 8071313508, FAX: 7966303366, E-Mail: sneha.gupta2@iqvia.com to conduct clinical trial of the new drug or investigational new drug as per Protocol no.: 218702, Version number:1.0, Dated 22-JUN-2022 in the below mentioned clinical trial sites.

CT No.: CT- 26/2022

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.

VENUGOPAL G SOMANI

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DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb2557487 32c456d249073e55e953d9cb5b58748ee3113 c, postalCode=110002, st=DELHI, serialNumber=e97241aa0c0bba41522525ffc a0705074b4997e6b2f4b5c8d81cf282adeaf5d cn=VENUGOPAL G SOMANI
Date: 2022.11.29 ...

(D. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

Place: New Delhi
Date: 29-NOV-2022

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Inactivated Influenza Vaccine (Split Virion) I.P. (Quadrivalent)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Suspension for Injection n a pre-filled syringe for intramuscular route of administration.</td></tr>
<tr><td>Composition:</td><td>Each dose of 0.5 ml vaccine contains:

<table>
<tr><th>Name of ingredients</th><th>Quantity</th></tr>
<tr><td>A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/2570/2019, IVR-215)</td><td>15 µg HA*</td></tr>
<tr><td>A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/6/2021, IVR-227)</td><td>15 µg HA*</td></tr>
<tr><td>B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021, BVR-26)</td><td>15 µg HA*</td></tr>
<tr><td>B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)</td><td>15 µg HA*</td></tr>
<tr><th>Name of Inactive ingredients</th><th>Quantity</th></tr>
<tr><td>Polysorbate 80 (Tween-80),EP</td><td>< 550 µg</td></tr>
<tr><td>Octoxinol 10 (Triton® X-100),EP</td><td>< 115 µg</td></tr>
<tr><td>RRR-α-Tocopheryl hydrogen succinate, USP/EP</td><td>< 135 µg</td></tr>
<tr><td>Sodium chloride, USP/EP</td><td>3.750 mg</td></tr>
<tr><td>Magnesium chloride hexahydrate, USP/EP</td><td>0.050 mg</td></tr>
<tr><td>Disodium phosphate dodecahydrate, USP/EP</td><td>1.300 mg</td></tr>
<tr><td>Potassium dihydrogen phosphate, EP</td><td>0.200 mg</td></tr>
<tr><td>Potassium chloride USP/EP</td><td>0.100 mg</td></tr>
<tr><td>Formaldehyde, USP/EP</td><td>≤ 0.005 mg</td></tr>
<tr><td>Sodium deoxycholate</td><td>≤ 0.065 mg</td></tr>
<tr><td>Ovalbumin</td><td>≤ 0.050 µg</td></tr>
<tr><td>Gentamicin sulphate, USP/EP</td><td>< 0.000 (traces)</td></tr>
<tr><td>Hydrocortisone, USP/EP</td><td>< 0.000 traces</td></tr>
<tr><td>Water for Injections, USP/EP</td><td>q.s. to 0.50 ml</td></tr>
</table>
* Haemagglutinin</td></tr>
<tr><td>Indication(s):</td><td>For active immunization of adults and children from 6 months of age for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine</td></tr>
</table>

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee registration detailed	Name of Principal Investigator
1	Calcutta School of Tropical Medicines, 108 Chittaranja Avenue Kolkata-700073, West Bengal, India.	Clinical research Ethics Committee, Calcutta School of Tropical Medicines, 108 Chittaranja Avenue Kolkata-700073, West Bengal,	Dr. Santanu Munsi

		India. [ECR/194/Inst/WB/2013/RR-20]	
2	Galaxy Hospital, A Venture of Galaxy Life Care Services Pvt. Ltd., Plot no.-5,6,&7, Dhayal Enclave Mahmoorg anj. Varanasi-221010, India.	Ethics Committee Galaxy Hospital, Galaxy Hospital, A Venture of Galaxy Life Care Services Pvt. Ltd., Plot no.-5,6,&7, Dhayal Enclave Mahmoorg anj. Varanasi-221010, India. [ECR/877/Inst/UP/2016/RR-20]	Dr. Ritandhar Mishra
3	KLES Prabhakar Kore Hospital & Medical Research Centre , J Nehru Nagar, Belgaum Karnatka-590010	Institutional Ethics Committee KLES Prabhakar Kore Hospital & Medical Research Centre , J Nehru Nagar, Belgaum Karnatka-590010 [ECR/211/Inst/KA/2013/RR-19]	Dr Madhav Prabhu
4	SRM Medical College Hospital & Research Center , RM University SRM Nagar , Kattankulathur-603203 Kancheepurm , Tamil Nadu, India	Institutional Ethics Committee SRM Institute of Medical Science (SIMS) No.1, Jawaharlal Nehru Salai, Vadapalani Chennai-600026, Tamil Nadu, India [ECR/431/Inst/TN/2013/RR-19]	Dr. Satyajit Mohapatra
5	Suyog Hospital 2 Floor, B Wing Krushi Utpapanna Bazar, Samiti Sankul Dindori Road, Panchavati, Nashik 422003, Maharashtra, India	Suyog Hospital Institutional Ethics Committee, Suyog Hospital 2 Floor, B Wing Krushi Utpapanna Bazar, Samiti Sankul Dindori Road, Panchavati, Nashik 422003, Maharashtra, India [ECR/965/Inst/MH/2017/RR-20]	Dr. Kailash Jadish Rathi
6	Supe Heart & Hospital & Research Center, Opposite Adhar aashram, Near Runghta High School, Ashok Stambh, Panchavati, Nashik-422002, Maharashtra, India.	Supe Hospital Institutional Ethics Committee Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road Chargawa Gorakhpur- 273001, Uttar Pradesh, India [ECR/272/Inst/MH/2013/RR-19]	Dr. Pravin Dinkar Supe
7	King George Hospital, Near Collect orate, Maharanipeta, Visakhapatnam-530002 Andhra Pradesh, India	IEC King George Hospital, Near Collectiorate, Maharanipeta, Collector Office Junction Visakhapatnam-530002 Andhra Pradesh, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. Yandrapati Gnana Sundara Raju

In addition to point 3, the permission is subject to following conditions:

I. The clinical trial should be conducted as per approved protocol titled “A single-arm, open-label, multi-centre, Phase IV trial to evaluate the reactogenicity, safety, and immunogenicity of Quadrivalent seasonal influenza vaccine (Fluarix Tetra) in participants aged 65 years and older in India” [Protocol no.: 218702, Version number: 1.0, Dated 22-JUN-2022]

II. Firm is required to submit the following documents/information:

a) Copy of duly signed copy of contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium,

payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.

b) Copy of the Ethics committee approval for the proposed Phase IV clinical trial for remaining clinical trial sites.

VIII. The formulation intended to be used in the clinical trial shall be manufactured using validated procedures under GMP conditions and shall have ongoing stability programme.

IX. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba4152252 5ffca0705074b4997e6b2f4b5c8d81cf282 2deaf5c3e, cn=VENUGOPAL G SOMANI
Date: 2022.11.29 17:54:26 +05'30'

(Dr. V. G. Somani)

Place: New Delhi
Date: 29-NOV-2022

Drugs Controller General (India)
Central Licensing Authority

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA