File No: BIO/CT/21/000057
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 Mr. Michael C Vernekar of M/s Serum Institute Of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar Pune (India) - 411028 Telephone No.: 020- 26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 E-Mail :MICHAEL.VERNEKAR@SERUMINSTITUTE.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: IPV 01, Version No. 2.0, Dated 03- Sept-2021 in the below mentioned clinical trial sites.

CT No.: CT-08/2022

2. Details of new drug or investigational new drug and clinical trial sites [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: 25-MAR-2022

VENUGOPAL G SOMANI

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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority
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Annexure:

Details of New Drug or Investigational New Drug

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Inactivated Salk Polio Vaccine (Adsorbed)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Liquid, Solution for Injection</td></tr>
<tr><td>Composition:</td><td>Each 0.5ml vaccine contains:
<table>
<tr><th>Name of Active Ingredient</th><th>Quantity</th></tr>
<tr><td>Inactivated Poliomyelitis Virus Type 1, Mahoney strain</td><td>10 DU</td></tr>
<tr><td>Inactivated Poliomyelitis Virus Type 2, MEF -1 strain</td><td>2DU</td></tr>
<tr><td>Inactivated Poliomyelitis Virus Type 3, Saukett strain</td><td>10DU</td></tr>
<tr><td>Name of Inactive Ingredients</td><td>Quantity</td></tr>
<tr><td>Aluminium hydroxide l(OH)3</td><td>NMT 1.25 mg</td></tr>
<tr><td>2-Phenoxyethanol</td><td>2.5mg</td></tr>
<tr><td>Formaldehyde</td><td>12.5mcg</td></tr>
<tr><td>Dilution Medium for IPV (Salk-Adsorbed)</td><td>q.s. to 0.5ml</td></tr>
</table>
*Cultivated on Vero cells</td></tr>
<tr><td>Indications:</td><td>Prevention of Poliomyelitis caused by Poliovirus Types 1, 2 and 3.</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	Department of Community Medicine and School of Public Health, Post Graduate Institute of Medical Education and Research, Chandigarh- 160012	Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research, Room no. 6006, IEC Office, 6th Floor, P N Chuttani Block Chandigarh-160012, India	Dr. Madhu Gupta
2	Mysore Medical College And Research Institute, Irwin Road, next to Railway Station, Mysuru, Karnataka - 570001	Institutional Ethics Committee, K.R. Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore-570001, Karnataka, India	Dr. Pradeep N
3	T N Medical College & BYL Nair Charitable Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai, Maharashtra -400008	Institutional Ethics Committee, TNMC Nair Hospital T N Medical college & BYL Nair Hospital, Dr A L nair Road Mumbai central Maharashtra-400008	Dr. Sushma Sav

4	IMS & SUM Hospital, K 8,Kalinga Nagar, Ghatikia, Bhubaneshwar, Odisha -751003	Institutional Ethics Committee IMS and SUM Hospital K8 Kalinganagar Shampur Bhubaneswar, Khordha Oriss-751003	Dr. Sandeep Kumar Panigrahi

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

i. The clinical trial shall be conducted as per protocol titled " A Phase II/III, Multicenter, Double Blind, Randomized, Active Controlled Study to evaluate Safety and Immunogenicity of SII Inactivated Salk Polio Vaccine (Adsorbed) in comparison with Sii Licensed Inactivated Poliovirus Vaccine(IPV)” [Protocol no.: IPV:01, Version no.: 2.0, Final dated 03-Sept-2021].

ii. The clinical trial sites for both IPV vaccines studies should be separate and the interim results of phase II should be submitted before proceeding to Phase III study as per the recommendations of SEC (Vaccine) experts dated 02.07.2021

iii. Firm is required to submit the following information/documents:
   a) Transport validation report of monovalent bulk shipped to SIIPL from M/s Bilthoven Biologicals B. V.
   b) Complete analytical validation report.
   c) The 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.

iv. Firm is required to ensure inactivation process of Bulk vaccine batches manufactured at M/s Bilthoven Biologicals B.V received at M/s SIIPL, Pune and to submit Quality Risk assessment report.

v. DSMB shall be constituted for assessment of safety data of clinical trial.

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

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

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Date: 2022.03.28 10:37:00 +05'30'

Place: New Delhi
Date: 25-Mar-2022

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