File No: BIO/CT/24/000153
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

To

M/s Serum Institute of India Pvt. Ltd.,
212/2, Hadapsar, Pune, Off. Soli Poonawalla Road.,
Maharashtra (India) –411028

Subject: Permission to conduct a clinical trial titled "A Phase 2/3, Double-Blind, Randomized, Active-Controlled, Multicentric study to evaluate the Safety, Immunogenicity and Lot-to-Lot consistency of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy individuals aged 6 months to 65 years", Protocol No. TCV-02, Version: 1.0, dated 21st Oct 2024"- regarding.

Reference: Your Application No. BIO/CT04/FF/2024/46150 dated 19.11.2024 on the subject mentioned above.

Sir,

Please refer to your application no. No. BIO/CT04/FF/2024/46150 dated 19.11.2024, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase II/III Clinical Trial of "Typhoid Conjugate Vaccine (Bivalent)" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.05.26 11:21:29 +05'30'

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

File No: BIO/CT/24/000153
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 grant permission to M/s Serum Institute of India Pvt. Ltd.,212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) –411028 to conduct clinical trial of the new drug or investigational new drug as per Protocol No. TCV-02, Version: 1.0, dated 21st Oct 2024. in the below mentioned clinical trial sites.

CT No.: CT- 10/2025

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.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Typhoid Conjugate Vaccine (Bivalent)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Liquid</td></tr>
<tr><td>Composition:</td><td>Composition:

Each dose of 0.5 ml vaccine contains:
<table>
<tr><th>Vaccine Ingredient</th><th>Quantity per dose</th></tr>
<tr><td colspan="2">Active Ingredients</td></tr>
<tr><td>Purified Vi polysaccharide from Salmonella Typhi conjugated to Tetanus Toxoid* (Vi -TT Purified Bulk Conjugate)</td><td>25 µg</td></tr>
<tr><td>Purified O-Specific Polysaccharide from Salmonella Paratyphi A is conjugated to Diphtheria Toxoid# (OSP-DT Purified Bulk Conjugate)</td><td>25 µg</td></tr>
<tr><td colspan="2">Inactive Ingredients</td></tr>
<tr><td>Tris Buffer</td><td>0.30 mg</td></tr>
<tr><td>Mannitol</td><td>25 mg</td></tr>
<tr><td>2 Phenoxyethanol</td><td>2.5 mg</td></tr>
<tr><td>Water for Injection</td><td>q.s.</td></tr>
</table>
Tetanus Toxoid12.5 µg to 50 µg
#Diphtheria Toxoid10 µg to 50 µg</td></tr>
<tr><td>Presentation:</td><td>3 mL glass vial</td></tr>
<tr><td>Indication(s):</td><td>SIIPL's Typhoid Conjugate Vaccine (Bivalent) is indicated for active immunization against Salmonella typhi and Paratyphi A infection in infants, children and adults (6 months to 65 years age group)</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	Vadu Rural Health Program, Shirdi Sai Baba Rural Hospital, A division of KEM Hospital, Pune, Village-Vadu (Budruk), Tal-Shirur, Pune-412216, Maharashtra, India.	KEM Hospital Research Center Ethics Committee, Pune 411011, Maharashtra, India [ECR/272/Inst/MH/2013/RR-22]	Dr Anand Kawade
2	King George Hospital, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh, India.	Institutional Ethics Committee, King George Hospital, Visakhapatnam-530002, Andhra Pradesh [ECR/197/Inst/KGH/2013/RR-20]	Dr B S Chakravarthy

3	Institute of Child Health, 11 Dr Biesh Guha Street, Kolkata 700017, West Bengal, India	Institutional ethics committee, Institute of Child Health, Kolkata, West Bengal-700017 [ECR/359/Inst/WB/2013/RR-24]	Dr Kheya Uttam Ghosh
4	Department of Pediatrics, Niloufer Hospital, Red Hills, Lakdikapool, Hyderabad, Telangana –500004, India.	Institutional ethics committee, Osmania Medical College, Hyderabad, 500059, Telangana,][ECR/300/Inst/AP/2013/RR-24]	Dr N Ravi Kumar
5	Department of Clinical Pharmacology, Seth G. S. Medical College and KEM Hospital, Acharya Donde Marg, Parel East, Parel, Mumbai, Maharashtra 400012, India.	Institutional Ethics Committee-1, Seth GS Medical College and KEM Hospital, Mumbai 400012EC [ECR/229/Inst/MH/2013/RR-24]	Dr Nithya Gogtay
6	Meenakshi Mission Hospital & Research Centre, Lake area, Melur Road, Madurai, Tamil Nadu, India	Meenakshi Mission Hospital & Research Centre Ethics Committee, Madurai, Tamil Nadu [ECR/398/Inst/TN/2013/RR-24]	Dr Uma Muralidharan
7	Marwari Hospital, Guwahati, Assam, Room No.: 520, Clinical Research Unit,5th Floor, Marwari Hospitals, Sati Joymati Road, Athgaon,Guwahati, Assam, India.	ECRC-HEC, Marwari Hospitals, S J Road, Athgaon, Guwahati-781008 [ECR/487/Inst/AS/2013/RR-24]	Dr Ritesh Jain
8	Christian Medical College and Hospital, Ludhiana, Punjab-141008, India.	Institutional Ethics Committee, Christian Medical College and Hospital, Ludhiana 141008, Punjab, India [ECR/120/Inst/PB/2013/RR-24]	Dr Clarence Samuel
9	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences (PGIMS), Medical Rd, Rohtak, Haryana 124001, India.	Institutional Ethics Committee, Pt. B.D. Sharma Post Graduate Institute of Medical Sciences, University of Health Sciences, Rohtak. [ECR/293/Inst/HR/2013/RR-24]	Dr Savita Verma
10	Clinical Epidemiological Unit, Department of Community Medicine, OBG and Paediatrics Block, Kushabhadra Campus, KIIT Campus, 5, KIIT Road, Patia, Bhubaneswar, Odisha 751024, India	Institutional Ethics Committee, Kalinga Institute of Medical Sciences, Bhubaneshwar Khordha Orissa 751024, India [ECR/321/Inst/OR/2013/RR-20]	Dr Sonali Kar

11	Department of Pharmacology, 2nd floor, College Building, Lokmanya Tilak Municipal Medical College & General Hospital, Dr. Babasaheb Ambedkar Road, Sion Mumbai-400022, India	Institutional Ethics Committee Human Research, Lokmanya Tilak Municipal Medical College and General Hospital, Sion, Mumbai 400022. [ECR/266/Lokmanya/Inst/MH/2013/RR-24]	Dr Sudhir Pawar
12	National Institute of Cholera & Enteric Diseases, Division of Epidemiology, National Institute of Cholera & Enteric Diseases, P 33 CIT Road, Scheme XM, Beliaghata, Kolkata 700010, West Bengal, India	Institutional Ethics Committee-ICMR-National Institute of Cholera and Enteric Diseases (IEC-ICMR-NICED), Kolkata-700010, West Bengal. [ECR/416/Inst/WB/2013/RR-20[	Dr Shanta Dutta
13	Clinical Research Centre – HIMSR with CHRD-SAS Block B, Basement, Hamdard Institute of Medical Sciences and Research (HIMSR), with Centre for Health Research and Development -Society for Applied Studies (CHRD-SAS), Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062, India	Institutional Ethics Committee HIMSR and Associated HAH Centenary Hospital, Guru Ravidas Marg, Hamdard Nagar, South West Delhi, Delhi 110062, India. [ECR/1597/Inst/DL/2021]	Dr Sunil Kohli
14	Department of Community Medicine, JSS Medical College, JSS Hospital, Mahatma Gandhi Road, JSS Medical Institutions Campus, Shivarathreeshwara Nagara, Mysuru -570015, Karnataka, India.	Institutional Ethics Committee, JSS Medical College and Hospital, JSS Medical College, Mysore-57005, Karnataka, India [ECR/387/Inst/KA/2013/RR-22]	Dr Praveen Kulkarni

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

1. The Phase-II/III clinical trial should be conducted as per approved protocol titled “A Phase 2/3, double-blind, randomized, active-controlled, multicentric study to evaluate the safety, immunogenicity and lot-to-lot consistency of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy individuals aged 6 months to 65 years", Protocol No. TCV-02, Version: 1.0, dated 21st Oct 2024”.

2. The firm is required to constitute a DSMB to review the safety data.
3. To submit Phase II study report along with DSMB review for approval before initiation of Phase III study.
4. Firm is required to submit Ethics Committee approval for Phase II/III clinical trial.
5. To ensure that shelf life of the IMPD will cover duration of the study period of the clinical trial.
6. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and certified by CDL.
7. The firm shall use CDL, Kasauli certified validated batches in the Phase III clinical trial.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date: