

File No: BIO/CT/22/000121
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 Tech Square, Marathahalli- Sarjapur, Outer Ring Road Kadubeesanahalli Bangalore (India)- 560103, Telephone No.: 8071313508, FAX: 7966303366, E-Mail: sneha.gupta2@iqvia.com to conduct clinical trial – Phase III of the new drug or investigational new drug as per Protocol no.: DEN-302, Version no. 2.0, Dated 15-JUN-2023 in the below mentioned clinical trial sites.

CT No.: CT- 10/2023

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.

Place: New Delhi
Date:

RAJEEV SINGH
RAGHUVANS
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Dengue Tetravalent Vaccine (Live, Attenuated)																											
Therapeutic class:	Vaccine																											
Dosage form:	Sterile lyophilized compact cake that is reconstituted prior to injection with 0.65 ml of diluent (PFS) (37mM Sodium Chloride solution) for 0.5 ml dose through Subcutaneous route of administration.																											
Composition:	Each single-use vial contains: <table><tr><th>Name of Active ingredients</th><th>Quantity per dose</th></tr><tr><td>Serotype TDV - 1</td><td>≥3.3 log₁₀ PFU/dose</td></tr><tr><td>Serotype TDV - 2</td><td>≥2.7 log₁₀ PFU/dose</td></tr><tr><td>Serotype TDV - 3</td><td>≥4.0 log₁₀PFU/dose</td></tr><tr><td>Serotype TDV- 4</td><td>≥4.5 log₁₀PFU/dose</td></tr><tr><th>Name of Excipients</th><th>Quantity</th></tr><tr><td>α,α-Trehalose, dihydrate</td><td>82.9 mg/dose</td></tr><tr><td>Kolliphor P407 (F127)</td><td>5.00 mg/dose</td></tr><tr><td>Human Serum albumin</td><td>0.500 mg/dose</td></tr><tr><td>Potassium dihydrogen phosphate</td><td>0.880 μmoles/dose</td></tr><tr><td>Disodium hydrogen phosphate dihydrate</td><td>5.01 μmoles/dose</td></tr><tr><td>Potassium chloride</td><td>1.35 μmoles/dose</td></tr><tr><td>Sodium chloride</td><td>68.5 μmoles/dose</td></tr></table>		Name of Active ingredients	Quantity per dose	Serotype TDV - 1	≥3.3 log ₁₀ PFU/dose	Serotype TDV - 2	≥2.7 log ₁₀ PFU/dose	Serotype TDV - 3	≥4.0 log ₁₀ PFU/dose	Serotype TDV- 4	≥4.5 log ₁₀ PFU/dose	Name of Excipients	Quantity	α,α-Trehalose, dihydrate	82.9 mg/dose	Kolliphor P407 (F127)	5.00 mg/dose	Human Serum albumin	0.500 mg/dose	Potassium dihydrogen phosphate	0.880 μmoles/dose	Disodium hydrogen phosphate dihydrate	5.01 μmoles/dose	Potassium chloride	1.35 μmoles/dose	Sodium chloride	68.5 μmoles/dose
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Indication(s):	Prevention of dengue disease caused by any dengue virus serotype in individuals 4 years to 60 years of age.																											

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee registration detailed	Name of Principal Investigator
1	King Georges Medical University, Shahmeena Road, Chowk, Lucknow-226003, India	Institutional Ethics Committee, King Georges Medical University Shahmeena Road, Chowk, Lucknow-226003, India [ECR/262/Inst/UP/2013/RR-19]	Dr. Himanshu Dandu
2	Maulana Azad Medical College & Associated Lok Nayak Hospital, Bahadur Shah Zafar Marg, New Delhi - 110002, India	Institutional Ethics Committee, Maulana Azad Medical College & Associated Lok Nayak Hospital, Bahadur Shah Zafar Marg, New Delhi - 110002, India [ECR/329/Inst/DL/2013/RR-19]	Dr. Raghvendra Singh
3	KEM Hospital Research Centre, Sadar Moodliar Road, Rasta Peth, Pune, Maharashtra, 411011, India	KEM Hospital Research Centre Ethics Committee, Sadar Moodliar Road, Rasta Peth, Pune, Maharashtra, 411011, India. [ECR/272/Inst/MH/2013/RR-22]	Dr. Ashish Bavdekar

4	Suyog Hospital, 2nd floor, B-Wing, Krushi Utapanna Bazar Samiti Sankul, Dindori Road, Panchavati, Nashik-422003, Maharashtra, India	Suyog Hospital Institutional Ethics Committee, 2nd floor, B-Wing, Krushi Utapanna Bazar Samiti Sankul, Dindori Road, Panchavati, Nashik-422003, Maharashtra, India [ECR/965/Inst/MH/2017/RR-20]	Dr. Kailash Rathi
5	IPGME & R and SSKM Hospital, 244, AJC Bose Road, Kolkata-700020, India	IPGME & R and Research Oversight Committee IPGMEandR 244 Acharya J. C. Bose Road - Kolkata Kolkata West Bengal - 700020 India [ECR/35/Inst/WB/2013/RR-19]	Dr. Anupam Mandal
6	Institute of Medical Sciences and SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneswar-751003, India.	Institute of Medical Sciences and SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneswar-751003, India. [ECR/627/Inst/OR/2014/RR-20]	Dr. Jyotirnanjan Sahoo
7	King George Hospital, Clinical Research Room, Department of General medicine, Rajendra Prasad Ward, Maharanipeta, Visakhapatnam - 530002, Andhra Pradesh, India.	Institutional Ethics Committee, King George Hospital, Clinical Research Room, Department of General medicine, Rajendra Prasad Ward, Maharanipeta, Visakhapatnam - 530002, Andhra Pradesh, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. Konatham Rambabu
8	SRM Centre for Clinical Trials & Research, SRM Medical College & Hospital & bResearch Centre, SRM Nagar, Kattankulathur-603203, Chengalpattu, Tamil Nadu, India.	SRM Centre for Clinical Trials & Research, SRM Medical College & Hospital & bResearch Centre, SRM Nagar, Kattankulathur-603203, Chengalpattu, Tamil Nadu, India. [ECR/805/Inst/TN/2016/RR-22]	Dr. Satyajit Mohapatra

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 Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Investigate the Safety and Immunogenicity of a Dengue Tetravalent Vaccine (Live, Attenuated) (TDV) Administered Subcutaneously to Healthy Subjects Aged 4 to 60 Years in India" [Protocol no.: DEN-302, Version no. 2.0, Dated 15-JUN-2023].
- II. The firm is required to constitute a DSMB to review the safety data.
- III. 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.
- IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date:

RAJEEV SINGH
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

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