

File No: BIO/CT/23/000055
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 Licencing Authority hereby permits M/s. Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar, Pune (India) - 4110288 to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No. SII-qHPV/IN-04 Version 2.0, dated 12-Jul-2023 in the below mentioned clinical trial sites.

CT No.: CT- 09/2023

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:

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Quadrivalent Human Papillomavirus (Serotypes 6, 11, 16 & 18) Vaccine	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Injection	
Composition:	Each dose of 0.5 mL contains:	
	Name of Active ingredient	Quantity
	Human papillomavirus type 6 L1 protein	≥20 µg
	Human papillomavirus type 11 L1 protein	≥40 µg
	Human papillomavirus type 16 L1 protein	≥40 µg
	Human papillomavirus type 18 L1 protein	≥20 µg
	Name of Active ingredient	Quantity
Aluminium Hydroxide [as Al ⁺⁺⁺]	≤ 1.25 mg	
Indication(s):	Indicated for active immunization in the age group of 9-14 years (male and female), two doses schedule (0 and 6 months) and for age group of 15-26 years (male and female), three-dose schedule (0,2 and 6 months) for prevention of the disease caused by Human Papillomavirus type 6,11,16 and 18.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Christian Medical College, Ida Scudder Road, Vellore-632002, Tamil Nadu.	Institutional Review Board & Ethics Committee, Christian Medical College, Office of Research, First floor, Carman Block, Bagayam, Vellore-632002, Tamil Nadu. [ECR/326/Inst/TN/2013/RR-19]	Dr. Anitha Thomas
2	G. Kuppuswamy Naidu Memorial Hospital, No. 6327, Nethaji Road, Pappanaickenpalayam, Coimbatore - 641037, Tamil Nadu.	Institutional Ethics Committee G. Kuppuswamy Naidu Memorial Hospital, Post Box No-6327, Nethaji Road, Pappanaickenpalayam Coimbatore - 641037, Tamil Nadu. [ECR/209/Inst/TN/2013/RR-19]	Dr. Latha Balasubramani
3	Tata Memorial Hospital, Main Building 3rd floor, Dr. Ernest Borges Road, Parel, Mumbai - 400072, Maharashtra.	Institutional Ethics Committee, Tata Memorial Hospital, 3rd floor, Main Bldg, Dr. E. Borges Marg, Parel, Mumbai-400012, Maharashtra. [ECR/170/Inst/MH/2013/RR-22]	Dr. Sharmila Pimple
4	Prayas, Amrita Clinic, Karve Road, Chatrapati Sambhaji Maharaj Bridge (lakadi Pul) corner, near Panchaleshwar Temple, Deccan Gymkhana, Pune - 411004, Maharashtra.	Institutional Ethics Committee for Research Prayas, Prayas Clinic, Karve Road, Deccan Gymkhana, Pune - 411004, Maharashtra. [ECR/146/Indt/MH/2014/RR-20]	Dr. Smita Joshi

5	Department of Obstetrics and Gynaecology, 3rd Floor. F-Block, Nehru Building, Sector-12, PGIMER, Chandigarh - 160012, Punjab.	Institutional Ethics Committee, Room No. 6006, 6th floor, Research Block B, PGIMER, Sector-12, PGIMER, Chandigarh-160012, Punjab. [ECR/25/Inst/CH/2013/RR-20]	Dr. Vanita Suri
6	Department of Community Medicine, Kasturba Medical College, Manipal Academy of Higher Education, Madhava Nagar, Manipal-576104, Karnataka.	Manipal Academy of Higher Education Ethics Committee, Mezzanine floor, KMC Old Library Building, Madhava Nagar, Manipal- 576104, Karnataka. [ECR/191/Inst/KL/2013/RR-19]	Dr. Veena Kamath
7	Community Health Research Unit (CHRU) - KEM Hospital Research Centre. Third Floor, Shrivinayak Hospital, Mulewadi Road, P.O. Manchar, Taluka Ambegaon, District Pune-410503, Maharashtra.	KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, TDH building, Sardar Moodliar Road, Rasta Peth, Pune-411011, Maharashtra. [ECR/272/Inst/MH/2013/RR-22]	Dr. Aditi Apte
8	All India Institute of Medical Sciences, Department of Obstetrics & Gynaecology, Room No. 3076, 3d floor, Teaching Block, Ansari Nagar, New Delhi-110029.	Institute Ethics Committee, Room No. 102, 1 st Floor, Old O.T Block, All India Institute of Medical Sciences, Ansari Nagar, New Delhi - 110029. [ECR/538/Inst/DL/2014/RR-20]	Dr. Neerja Bhatla
9	Sapthagiri Institute of Medical Sciences & Research Centre, #15 Chikkasandra, Hesaraghatta Main road, Bangalore -560090, Karnataka.	Institutional Ethics Committee, Sapthagiri Institute of Medical Sciences & Research Centre, #15 Chikkasandra, Hesaraghatta Main road, Bangalore- 560090, Karnataka. [ECR/583/Inst/KA/2014/RR-20]	Dr. Rajini Uday
10	Bharati Vidyapeeth Deemed to be University Medical College Hospital & Research Centre, Pune-Satara Road, Dhankawadi - 411043, Pune, Maharashtra.	Institutional Ethics Committee, 4 th floor, Bharati Hospital & Research Centre, Pune-Satara Road, Dhankawadi- 411043, Pune, Maharashtra. [ECR/313/Inst/MH/2013/RR-19]	Dr. Sonali Palkar
11	Nazareth Hospital, Arbuthnot Rd, near Police Point, Nongkynrih, Laitumkhrah, Shillong, Meghalaya-793003.	INCLIN SOMAARTH Mawphlang Ethics Committee, East Khasi Hills Meghalaya-793121. [ECR/361/Indt/ML/2022]	Dr. Santanu Deb
12	JSS Hospital, Mahatma Gandhi Road, Mysuru - 570004, Karnataka.	Institutional Ethics Committee, 3 rd floor, JSS Medical College, S.S. Nagar, Mysuru-570015, Karnataka. [ECR/387/Inst/KA/2013/RR-22]	Dr. Subhash Chandra B.J

13	Noble Hospital Pvt Ltd. 153, Magarpatta City Road, Hadapsar, Pune – 411013, Maharashtra.	Institutional Ethics Committee, Noble Hospital Pvt. Ltd., Room No. 5, Clinical Research Department, 153, Magarpatta City Road, Hadapsar, Pune-411013, Maharashtra. [ECR/259/Inst/MH/2013/RR-19]	Dr. S. K. Raut
14	Hamdard Institute of Medical Sciences and Research (HIMSR) with Centre for health research & Development, Society for applied studies, Hakeem Abdul Hameed Centenary Hospital (HAHCH), Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062.	Institutional Ethics Committee, HIMSR and Associated HAH Centenary Hospital, Guru Ravidas Marg, Hamdard Nagar, New Delhi- 110062. [ECR/1597/Inst/DL/2021]	Dr. Sunil Kohli
15	Pt. B. D. Sharma, Post Graduate Institute of Medical Sciences, University of Health Sciences, Room No. 428, Department of Pharmacology, Rohtak-124001, Haryana.	Institutional Ethics Committee (IEC), PGIMS, University of Health Sciences, Rohtak-124001, Haryana. [ECR/293/Inst/HR/2013/RR-19]	Dr. Savita Verma
16	St. Theresa's Hospital, Sanathnagar, Hyderabad-500018, Telangana.	Ethics Committee, St Theresa's Hospital, Sanathnagar, Hyderabad- 500018, Telangana. [ECR/230/Inst/AP/2013/RR-22]	Dr. G. Bala Kishor
17	SRM Medical College Hospital & Research Centre, SRM Nagar, Kattankulathur, Chengalpattu-603203, Tamil Nadu.	SRM MCH & RC, Ethics Committee, Kattankulathur, Chengalpattu - 603203, Tamil Nadu. [ECR/431/Inst/TN/2013/RR-19]	Dr. Saswati Tripathy
18	Baramati Hospital, Behind Kavivarya Moropant Natyamandir, Ring Road, Baramati, Pune - 413102, Maharashtra.	Ethics Committee Baramati Hospital, Behind Kavivarya Moropant Natyamandir, Ring Road, Baramati, Pune-413102, Maharashtra. [ECR/1449/Inst/MH/2020]	Dr. Bhaskar Jedhe Deshmukh
19	MGM Medical College & Hospital, Clinical Trial Center, Department of Pharmacology, N- 6, CIDCO, Aurangabad-431003, Maharashtra.	MGM Ethics Committee for Research on Human Subject, N-6, CIDCO, Aurangabad - 431003, Maharashtra. [ECR/581/Inst/MH/2014/RR-20]	Dr. Deepak Tayade
20	Sanjeevani Children's Hospital. Plot No I4-15, Kushalnagar, Near Patidar Blavan, Jalna Road, Aurangabad- 431005, Maharashtra.	Aurangabad Health Care & Research LLP-Independent Ethics Committee, Shop No. 126, CTS No. 12482/1Chetan Trade Centre, Opp. S.F. School, Jalna Road, Aurangabad-431001, Maharashtra. [ECR/325/Inst/MH/2020]	Dr. Ganesh Kulkarni

21	Rajiv Gandhi Medical College and Chharapati Shivaji Maharaj Hospital, 2nd Floor, Department of Physiology, Old Thane Belapur Road, Kalwa, Thane-400605, Maharashtra.	Institutional Clinical Ethics Committee, RGMC & CSMH, Old Thane Belapur Road, Kalwa, Thane-400605, Maharashtra. [ECR/469/Inst/MH/2013/RR-20]	Dr. Swapnali Kadam
22	All India Institute of Medical Sciences, Department of Obstetrics & Gynaecology, Plot No. 2, Sector 20, MIHAN, Nagpur - 441108, Maharashtra.	Institutional Ethics Committee, AIIMS, MIHAN, Nagpur - 441108, Maharashtra. [ECR/1392/Inst/MH/2020]	Dr. Anusha Kamath
23	Krishna Institute of Medical Sciences Deemed To Be University, Pune – Bangalore Highway 04, Malkapur Road, Karad, Dist - Satara - 415539, Maharashtra.	Institutional Ethics Committee (IEC) of the Krishna Institute of Medical Sciences, Malkapur Road, Karad, Dist - Satara - 415539, Maharashtra. [ECR/307/Inst/MH/2013/RR-20]	Dr. Aparna Patange
24	Guru Nanak Hospital, NH-2, Near Palwal Bus Stand, Shiv Colony, Palwal-121102, Haryana.	The INCLEN Independent Ethics Committee, F-1/5, Second floor, Okhla Industrial Area, Phase-I, New Delhi-110020. [ECR/109/Indt/DL/2014/RR-20]	Dr. Abhishek Agarwal
25	KINS Hospital, Sevoke More, Hill Cart Rd, Ward 6, Siliguri, West Bengal-734001.	Siliguri Sumita Cancer R.W and E. Society, Ramkrishna Vedanta Ashrama Sarani, Pradhan Nagar, W/O-2, SLG-3 Siliguri, Darjeeling, West Bengal-743004. [ECR/345/Indt/WB/2021]	Dr. Sekhar Chakraborty
26	Vardhman Mahavir Medical College & Safdarjung Hospital, Department of Obstetrics & Gynaecology, Room 103, Ward 3, Ring Road, Ansari Nagar, New Delhi-110029.	Institutional Ethics Committee, Vardhman Mahavir Medical College & Safdarjung Hospital, Ring Road, Ansari Nagar, New Delhi-110029. [ECR/593/Inst/DL/2014/RR-20]	Dr. Saritha Shamsunder
27	PCMC'S Post Graduate Institute, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra.	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra. [ECR/1236/Inst/MH/2019]	Dr. Deepali Ambike
28	Tata Medical Center 14 Main Arterial Road (EW), New Town, Kolkata-700156, West Bengal.	Tata Medical Center-Institutional Review Board, 14 Main Arterial Road (EW), New Town, Kolkata-700156. [ECR/269/Inst/WB/2013/RR-19]	Dr. Sonia Mathai
29	Cancer Institute (WIA), 38, Sardar Patel Road, Adyar, Chennai-600036, Tamil Nadu.	Institutional Ethics committee Cancer Institute (WIA), Cancer Institute (WIA), No.1, East Canal bank Road, Adyar, Chennai, Tamil Nadu, PIN-600020	Dr. Jayashree N.

		[ECR/235/Inst/TN/2013/RR-19]	
30	Nargis Dutt Memorial Cancer Hospital, Agalgaon Road, Barshi, Solapur-413401, Maharashtra.	Institutional Ethics Committee of NDMCH, Nargis Dutt Memorial Cancer Hospital, Agalgaon Road, Barshi, Solapur-413401. [ECR/281/Inst/MH/2013/RR-20]	Dr. Yogesh Somani

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 Phase-IV, single-arm, multicentric study to assess the safety of SIIPs qHPV vaccine(CERVAVAC) when administered in a two-dose schedule to girls and boys aged 9-14 years and in a three-dose schedule to women and men aged 15-26 years [Protocol No. SII-qHPV/IN-04 Version 2.0, dated12-Jul-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 under GMP conditions.
- IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- V. Firm is required to submit Ethics Committee approval for clinical trial.

Place: New Delhi
Date:

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

