

File No: BIO/CT/24/000018

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 grants permission to 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:parag.nagarkar@seruminstitute.com conduct clinical trial of the new drug or investigational new drug as per Protocol No: MMR-01/23 Version 02 dated 17 Apr 2024 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

CT No.: CT-13/2024

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.

Date:
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze-Dried)	
Therapeutic class:	Vaccine	
Dosage form:	Freeze dried vaccine for subcutaneous route of administration. Presentation: Glass Vials (USP Type I) along with diluent vial. 1 dose with diluent (0.5 ml), 2 doses with diluent (1 ml), 5 doses with diluent (2.5 ml), 10 doses with diluent (5 ml).	
Composition:	Each dose of 0.5 mL Vaccine contains	
	Active ingredient	Quantity
	Live attenuated Measles virus (Edmonston-Zagreb strain) ##	NLT 1000 CCID ₅₀ /dose
	Live attenuated Mumps virus (L-Zagreb) propagated on chick embryo fibroblast cells	NLT 5000 CCID ₅₀ /dose
	Live attenuated Rubella virus (WISTAR RA 27/3 strain) ##	NLT 1000 CCID ₅₀ /dose
	Inactive ingredient	
	Partially Hydrolyzed Gelatin (I.P./B.P./Ph Eur/In-House)	2.5%
	Sorbitol (I.P./B.P./Ph Eur)	5 %
	Lactalbumin Hydrolysate (IH)	0.35%
	L-Alanine (B.P./Ph Eur)	0.1 %
	L-Histidine (B.P./Ph Eur)	0.21 %
	Tricine (IH)	0.3 %
	L-Arginine Hydrochloride (B.P./Ph Eur)	1.60 %
	Minimum Essential Medium (MEM)	q.s.
Sterile Water for injections I.P. (Diluent) ## The concentrations of Measles virus, Mumps virus and Rubella virus are expressed as cell-culture infective dose 50 % (CCID ₅₀). It is the quantity of virus suspension that is estimated to infect 50 % of cell culture.		
Indication:	For active immunization in children of 9 months to 6 years of age against Measles, Mumps and Rubella infections simultaneously.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	KEM Hospital Research Centre, Vadu Rural Health Program, Vadu Budruk, Taluka-Shirur, District- Pune 412216.	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. Anand Kawade

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2	Christian Medical College & Hospital, Brown Road, Ludhiana, Punjab- 141008	Institutional Ethics Committee 2nd floor, Nr. Ward no.15, room no-3201 Christian Medical College & Hospital, Brown Road, Ludhiana, Punjab- 141008 [ECR/120/Inst/PB/2013/RR-19]	Dr. Deepshikha Kamra
3	JSS Hospital, Mysuru- - 570004	Institutional Ethics Committee, JSS Medical College, JSS Hospital Sri Shivarathreeshwara Nagara, Mysuru Karnataka- 570015 [ECR/387/Inst/KA/2013/RR-22]	Dr. Sushma K
4	Department of Community Medicine, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha-442102, Maharashtra	Institutional Ethics Committee, (Department of Pharmacology) Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra -442102. India. [ECR/47/Inst/MH/2013/RR-24]	Dr. Anuj Mundra
5	Clinical Research Center- (Hamdard Institute of Medical Science and Research) HIMSR with (Society of Applied Science) SAS, Hakeem Abdul Hameed Centenary Hospital (HAHCH) Guru Ravidas Marg, Hamdard Nagar, New Delhi- 110080	Institutional Ethics Committee, HIMSR and Associated HAH Centenary Hospital, Guru Ravidas Marg, Hamdard Nagar, South West Delhi- 110062, India [ECR/1597/Inst/DL/2021]	Dr. Afreen Khan
6	Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata - 700017, West Bengal	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata - 700017, West Bengal [ECR/359/Inst/WB/2013/RR-24]	Dr. Kheya Ghosh Uttam

In addition to point 3, the permission is subject to following condition(s):

- I. The Phase IV clinical trial should be conducted as per title "A phase IV, double blind, randomized, active control clinical study comparing safety and immunogenicity of SII-Measles-Mumps-Rubella vaccine with PRIORIX (GSK) in healthy infants in India" as per Protocol No: MMR-01/23 Version 02 dated 17 Apr 2024.
- II. DSMB is required to be constituted to review the safety data of phase IV clinical trial.
- 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.

Date:
Place: New Delhi

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