

File No: BIO/CT/20/000079
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 M/s Serum Institute of India Pvt. Ltd. (SIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028, India. Tel: 020- 26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 E-Mail : SSJ@SERUMINSTITUTE.COM having bulk manufacturing of VPM1002 (rBCG) vaccine at M/s Serum Institute of India Pvt. Ltd., Building no. 14, 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028 and for VPM1002 (rBCG) vaccine at M/s Serum Institute of India Pvt. Ltd., M-SEZ-3, GF, S. no. 105-110, Manjari Budruk, Pune - 412307 to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: VPM1002-HCW Version: 2.0 dated 27Apr 2021 in the below mentioned clinical trial sites.

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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

(Dr. V. G. Somani)
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:	VPM1002 (rBCG) Vaccine	
Therapeutic class:	Vaccine	
Dosage form:	Liquid (Lyophilized powder for reconstitution with sterile water for injection (sWFI))	
Composition:	Each lyophilized vial (10 dose vial, single dose of 0.1 ml) contains:	
	Name of Active Ingredient	Quantity
	<i>M. bovis</i> rBCG ΔureC::Hly+	2 to 8 10 ⁶ CFU/vial
	Name of Inactive Ingredients	Quantity
	Dextran	8.3% (w/v in final bulk)
	Dextrose anhydrous	6.8% (w/v in final bulk)
Indications:	Prevention of TB infection in Health care Workers (HCWs)	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) Dhanvantri Nagar, Gorimedu, Puducherry 605006	Institutional Ethics Committee, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) Dhanvantri Nagar, Gorimedu, Puducherry 605006 ECR/342/Inst/PY/2013/RR-19	Dr. Sonali Sarkar
2	Kasturba Medical College Department of Community Medicine, Manipal Academy of Higher Education, Madhav Nagar, Manipal -576104	MAHE Ethics Committee, Manipal Academy of Higher Education, Madhav Nagar, Manipal -576104 ECR/191/Inst/KL/2013/RR-19	Dr. Veena Kamath
3	Pt. B D Sharma Postgraduate Institute of Medical Sciences (PGIMS), UHS, Rohtak -124001, Haryana	Institutional ethics Committee, Pt. B D Sharma Postgraduate Institute of Medical Sciences (PGIMS), UHS, Rohtak - 124001, Haryana ECR/293/Inst/HR/2013/RR-19	Dr. Savita Verma
4	Christian Medical College & Hospital Department of Community Medicine, Brown Road, Ludhiana -141008	Institutional Ethics Committee, Christian Medical College & Hospital Department of Community Medicine, Brown Road, Ludhiana -141008 ECR/120/Inst/PB/2013/RR-19	Dr. Clarence J Samuel

5	Post Graduate Institute of Medical Education & Research Department of Community Medicine, Room no. 130, Ground Floor, School of Public Health, Sector 12, Chandigarh 160012	Institutional Ethics Committee, Post Graduate Institute of Medical Education & Research Department of Community Medicine, Room no. 130, Ground Floor, School of Public Health, Sector 12, Chandigarh 160012 ECR/25/Inst/CH/2013/RR-20	Dr. Madhu Gupta
6	Mahatma Gandhi Institute of Medical Sciences, Dr. Sushila Nayar School of Public Health, Department of Community Medicine, Mahatma Gandhi Institute of Medical Sciences, Sewagram 442102, Wardha	Institutional Ethics Committee, Mahatma Gandhi Institute of Medical Sciences Dr. Sushila Nayar School of Public Health, Department of Community Medicine, Mahatma Gandhi Institute of Medical Sciences, Sewagram 442102, Wardha ECR/47/Inst/MH/2013/RR-19	Dr. Abhishek Raut,
7	B. J. Medical College & Sassoon General Hospitals B.J Government Medical College and Sassoon General Hospitals & College of Nursing, Jai Prakash Narayan Road, Near Pune Railway Station, Pune - 411001	Institutional Ethics Committee, B. J. Medical College & Sassoon General Hospitals B.J Government Medical College and Sassoon General Hospitals & College of Nursing, Jai Prakash Narayan Road, Near Pune Railway Station, Pune -411001 ECR/433/Inst/MH/2013/RR-19	Dr. Sameer Joshi

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

- i. The clinical trial shall be conducted as per protocol titled "A Multicenter, Phase III, Double-blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of VPM1002 Vaccine in the Prevention of Tuberculosis Infection in Health Care Workers" vide Protocol Number: VPM1002-HCW Version: 2.0 dated 27Apr 2021.
- ii. Firm shall submit report of reconstituted stability data of VPM1002 (rBCG) manufactured at Manjari/Hadapsar facilities before start of clinical trial in the country.
- iii. DSMB shall be constituted for assessment of safety data of clinical trial.
- iv. 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.
- v. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 16.07.2021

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority