

File No: BIO/CT/21/000084
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 grant permission to Ms. Deepti Nair of M/s Glaxosmithkline Pharmaceuticals Limited, 252, Dr. Annie Besant Road, Worli, Mumbai-400030, Maharashtra, India. Mumbai (India) - 400030 Telephone No.: null FAX: null E-Mail: RAININDIA.PHARMA@GSK.COM to conduct clinical trial of the new drug or investigational new drug as per Protocol No.:214461 (ZOSTER-081), Version No. 01, Dated 08-June-2021 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

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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.
4. It may kindly be noted that merely granting permission to conduct clinical trials with the vaccine does not convey or imply that based on the clinical trial data generated with the vaccine, permission to market this vaccine in the country with automatically be granted to you.

Date: 16-Sept-2021
Place: New Delhi

(Dr. V. G. Somani)
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:	Herpes Zoster Vaccine (Recombinant, Adjuvanted)	
Therapeutic class:	Vaccine	
Dosage form:	Powder and suspension for suspension for injection	
Composition:	Each dose of 0.5 ml reconstituted vaccine contains:	
	Active ingredient	Quantity
	Glycoprotein E (gE)	50 µg
	Sucrose	20 mg
	Polysorbate 80 (PS80)	0.08 mg
	3-O-desacyl-4'-monophosphoryl lipid A (MPL)	50 µg
	Purified Quillaja Saponin (QS-21)	50 µg
	Dioleoyl phosphatidylcholine (DOPC)	1 mg
	Cholesterol	0.25 mg
	Sodium chloride (NaCl)	4.385 mg
	Sodium Dihydrogen phosphate dihydrate (NaH ₂ PO ₄ .2H ₂ O)	0.160 mg
	Dipotassium phosphate (K ₂ HPO ₄)	0.116 mg
	Disodium phosphate anhydrous (Na ₂ HPO ₄)	0.15 mg
	Potassium dihydrogen phosphate (KH ₂ PO ₄)	0.54 mg
	Water for injection (WFI)	q.s.
Indication:	For prevention of Herpes Zoster (HZ) and post-herpetic neuralgia (PHN) in adults 50 years of age or older.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Sir Ganga Ram Hospital, Delhi Sir Ganga Ram Hospital Marg, Old Rajinder Nagar, New Rajinder Nagar, New Delhi, Delhi 110060, India.	Sir Gangaram Hospital Ethics Committee, Sir gangaram hospital, old Rajinder nagar, New Delhi -11006 [ECR/20/Inst/DL/2013/RR-19]	Dr Subhash Chandra Bharija
2	Lifepoint hospital, No. 145, Sr, 1, Mumbai Pune Bypass Rd, near Sayaji Hotel, Wakad, Pune, Maharashtra 411057, India.	LPR Ethics committee, Life point hospital, 145/1, Mumbai banglore highway, Near Syaji Hotel, Wakad, Pune, Maharashtra- 41105. [ECR/751/Inst/MH/2015/RR-18]	Dr Sonal Shendkar
3	Ishwar Institute of Health Care, MH SH 16, Padegaon, Aurangabad, Maharashtra 431002, India.	Ethics Committee of Ishwar Institute of HealthCare Ishwar Institute of Health Care 3rd Floor, Plot No.07, Gut No. 6/1 Padhegaon, Beside Panjabi	Dr Prashant Palwade

		Bhavan Jaysingpura Aurangabad Maharashtra- 431002,India[ECR/988/Inst/MH/ 2017/RR-20]	
4	Lotus multispecialty hospital, Ahmedabad Beside Swastik School, Motera Stadium Rd, opp. Baliyadev Temple, Ahmedabad, Gujarat 380005, India.	Lotus Ethic committee, Lotus Multispeciality hospital, Room no 2, 2nd floor, Stadium road, Montera Sabarmati Ahmedabad Gujarat -380005 [ECR/990/Inst/GJ/2017/RR-20]	Dr Neha Sharma
5	Ananta institute of medical sciences, Udaipur, Rajasthan, India.	Ethic committee of Ananta lec , Ananta Institute of Medical Sciences N.H 8, Village Kaliwas Tehsil Nathdwam Mjsamand Rajsamand, Rajasthan -313202. [ECR/1394/InsuRJ/2020]	Dr Manish Jain
6	Medipoint Hospital Dept. of Dermatology, 41/1, New D.P. Road, Aundh, Pune-41 1007 Pune, Maharashtra, India.	Penta-Med Ethics Medipoint Hospitals Pvt Ltd. [ECR/357/Inst/MH/2013/RR-20]	Dr Ketan Kshirsagar
7	Vadu Rural Health Program,KEM Hospital Research Centre, Pune 411011, India	KEM Hospital Research Centre Ethics Committee KEM Hospital Research Centre Sardar Moodliar Road Rasta Peth, Pune 411011, India [ECR/272/Inst/MH/2013/RR-19]	Dr Anand Kawade
8	Jehangir Hospital 32, Sasoon Road Opposite Railway Station, Central Excise Colony, Sangamvadi, Pune, Maharashtra 411001, India.	Institutional Ethics Committee, Jehangir Clinical Development Centre Institutional Review Board Pune [ECR/352/Inst/MH/2013/RR-19]	Dr Vaidya Prakash
9	Grant Medical College and Sir Jamshedjee Jeejeebhoy Group of Hospitals, J J Marg, Nagpada - Mumbai Central, Off Jijabhoy Road,Mumbai, Maharashtra 400008, India	Institutional Ethics Committee ,GGMC, Mumbai Grant Govt Medical College JJ Road, JJ Hospital compound Mumbai Central, Mumbai, Maharashtra - 400008 India. [ECR/382/Inst/MH/2013]	Dr Lalit Sankhe

In addition to point 4, the permission is subject to following condition(s):

- I. The Phase III clinical trial should be conducted as per title "A phase 3, randomised, observer-blind, placebo- controlled, multi-centre study to evaluate the immune response and safety of the Herpes Zoster subunit vaccine when administered intramuscularly on a 2-dose schedule in adults aged 50 years and older in India" as per Protocol No.: 214461 (ZOSTER-081), Version No. 01, Dated 08-June-2021.
- II. The clinical trial sites should be geographically distributed as per the recommendations of SEC (Vaccine) meeting held on 06-August-2021.

The firm is required to comply and submit the following information/documents:

1. The Process Performance Qualification for both [Sterile gE formulated bulk (sterile filtration process) (formulation) and Bioburden controlled process (non-sterile gE formulated bulk)] manufacturing processes.
 2. The following documents/information as per the requirements of WHO TRS 999 and Schedule M of Drugs and Cosmetics Rules, 1945:
 - a) QRM assessment reports
 - b).Change over procedures
 - c). Cleaning validation protocol and reports for campaign based manufacturing.
 - d). Frequency of campaign decided for manufacturing of Drug product along with other products.
 3. The capacity of PETG bottles used for storage of bulk Drug substance.
 4. The detailed qualification and validation report for reference standards.
- III. DSMB is required to be constituted to review the safety data of phase I clinical trial.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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