File No: BIO/CT/22/000084

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 permits M/s TechInvention Lifecare Pvt. Ltd., # 1004, The Summit Business Bay, Off. WEH Metro Station, Andheri Kurla Road, Andheri E, Mumbai – 400093 E-mail: syed@techinvention.biztoconduct clinical trial of the new drug or investigational new drug as per Protocol No. CRN_3110/2021, Version 1.0, dated 27-10-2021in the below mentioned clinical trial sites.

CT No.: CT-05/2023

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: 28-JUNE-2023

RAJEEV SINGH RAGHUVANSHI

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

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Varicella Vaccine, Live Attenuated	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized powder for Injection (to be reconstituted with Sterile Water for Injection)	
Composition:	Each 0.5 mL of Varicella Vaccine, Live in vial after reconstitution contains:	
	Ingredients	**Quantity**
	Live attenuated VZV (Oka strain)	3.6 ~ 4.8 lg PFU/mL
	Sucrose	5% (g/mL)
	Sodium glutamate	0.072% (g/mL)
	Sodium chloride	0.228%(g/mL)
	Potassium chloride	0.006% (g/mL)
	Disodium hydrogen phosphate	0.628%(g/mL)
	Potassium dihydrogen phosphate	0.058%(g/mL)
	Sterilized water for Injection I.P	0.5mL
Indications:	For active immunization against infection caused by varicella in individuals aged 1 year (12 months) to 12 years.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Dept. of Community Medicine, All India Institute of Medical Sciences, Patna Bihar-801507.	Institute Ethics Committee All India Institute of Medical Sciences, Phulwarisharif Patna Bihar-801507,India [ECR/1387/Inst/BR/2020]	Dr. Chandramani Singh
2	Jeevan Rekha Hospital, Dr. B R Ambedkar Road, Belagavi, Karnataka -590010	Institutional Ethics Committee, Dr. B.R. Ambedkar Road Opp Civil Hospital, Belagavi(Belgaum) Karnataka-590002 India [ECR/1242/Inst/KA/2019]	Dr. Abhishek T. Chavan
3	Department of Pediatrics, Niloufer Hospital, Red Hills, Lakdikapool, Hyderabad -500004	Institutional Ethics Committee Osmania Medical College, Koti, Telangana-500095 India. [ECR/300/Inst/AP/2013/RR-19]	Dr. N Ravi Kumar
4	Department of Pediatrics, S. N. Medical college, Agra,	Institutional Ethics Committee, S. N. Medical	Dr. Ram Kshitij Sharma

	Moti Katra, Mantola, Agra, UP-282003	college, Agra, UP-282003 [ECR/1409/Inst/UP/2020]	
5	Aatman Hospital, 5, Anveshan Row House, Opposite umiya mata mandir, Bopal Ghuma main road, Ahmedabad-380058	Institutional Ethics Committee Aatman Hospital 5, Anveshan Row House, Opposite umiya mata mandir, Bopal Ghuma main road, Ahmedabad-380058. [ECR/1565/Inst/GJ/2021]	Dr. Shreyans Shah
6	New Leelamani hospital 14 /116,c-1 parade haurahacivil lines Kanpur, UP-208001	Institution Ethical Committee New Leelamani hospital 14 /116, c-1 parade chauraha civil lines Kanpur, UP 208001 [ECR/1696/Inst/UP/2022]	Dr. Raghu Raj Singh

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

1. The Phase III clinical trial should be conducted as per title “A prospective, randomized, single blind, parallel, active controlled, multicentre, non Inferiority Phase III study to evaluate the immunogenicity and safety of Live Attenuated Varicella Vaccine of Sinovac Biotech Ltd, China compared to VARIPED® Vaccine (Varicella Vaccine Live I.P by MSD Pharmaceuticals Pvt., Ltd., India) in healthy paediatric subjects in India” [Protocol No. CRN_3110/2021, Version 1.0, dated 27-10-2021].
2. The firm is required to submit test license in Form CT-17 for import of Varicella Vaccine, Live Attenuated for examination, test and analysis and for clinical trial purpose.
3. Firm is requested to submit the stability data of reconstituted Varicella vaccine, Live Attenuated using the proposed diluent from India.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures and shall have ongoing stability program.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date:

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
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