

File No: BIO/CT/23/000048
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 NOVO MEDI SCIENCES PRIVATE LIMITED, Royal Status Building, Pandit Wamanrao Sadolikar Marg, Lokmanya Tilak Colony, Dadar, Mumbai, Maharashtra- 400014 (India), Telephone No.: 022-43426100 FAX: 022-43426100 E-Mail : sunilvhb@gmail.com to conduct clinical trial of the new drug or investigational new drug as per protocol number : CRNI/CTP/013, Version Number: 1.0 dated 20 Mar 2023 in the below mentioned clinical trial sites.

CT No.: CT- 13/2023

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:	Varicella Vaccine (Live, Attenuated)	
Therapeutic class:	Vaccine	
Dosage form:	Freeze-dried injection (Subcutaneous)	
Composition:	Each dose of 0.5 ml contains	
	Name of Active ingredient	Quantity
	Oka virus strain	Not less than 3.3 lg PFU
	Name of Inactive ingredient	
	Sucrose	3.8 mg
	Trehalose	22.5 mg
	Sodium Glutamate	4.5 mg
	Urea	0.9 mg
	Arginine	0.9 mg
	Glucose	1.85 mg
	Human Albumin	5.0 mg
	Diluent	
	Sterile Water for Injection	0.5 ml
Indication(s):	The vaccine is indicated for the active immunization against varicella of healthy, varicella susceptible subjects from age of 12 months.	

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 and Family Medicine, All India Institute of Medical Sciences, Patna Bihar-801507	IEC-AIIMS-P, All India Institute of Medical Sciences, Patna, Phulwarisarif, Patna, Bihar – 801507 [ECR/1387/Inst/BR/2020]	Dr. Chandramani Singh
2	Aatman Hospital, 5, Anveshan Row House, Bopal Gam BRTS, Bopal Ghuma Road, Bopal, Ahmedabad -380058, Gujarat, India	Institutional Ethics Committee Aatman Hospital, Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir, Bopal Ghuma Main Road, Bopal Ghuma, Ahmedabad, Gujarat – 380058. [ECR/1565/Inst/GJ/2021]	Dr. Shreyans Shah
3	Jeevan Rekha Hospital, Opposite Civil Hospital, Dr. B R Ambedkar Road, Belagavi, Karnataka-590002	Ethics Committee Jeevan Rekha Hospital, Opposite Civil Hospital, Dr. B. R. Ambedkar Road, Belagavi, Karnataka – 590002. [ECR/1242/Inst/KA/2019/RR-22]	Dr. Abhishek T. Chavan
4	Department of Pediatrics, Cheluvamba Hospital, Opp Mysore Medical College and Research Institute, Irwin Road, Mysore-570001	IEC-MMC and RI and Associated Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore, Karnataka – 570001. [ECR/134/Inst/KA/2013/RR-19]	Dr. Pradeep N

5	New Leelamani Hospital Pvt. Ltd., 14/116,C-1, Parade Chauraha, Civil Lines, Kanpur, Uttar Pradesh-208001	Institutional Ethics Committee- Leelamani Hospital, New Leelamani Hospital, 14/116 B, C, C-1D, 1 Civil Lines, Kanpur, Uttar Pradesh – 208001. [ECR/1696/Inst/UP/2022]	Dr. Raghu Raj Singh
6	ESIC Medical College & Hospital, MRU (Multidisciplinary Research Unit), Basement, Boys Hostel, NH-3, NIT, Faridabad, Haryana, India-121001	Institutional Ethics Committee for ESIC Faridabad, ESIC Medical College and Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana – 121001. [ECR/1539/Inst/HR/2021]	Dr. Anil Kumar Pandey
7	Rana Hospital Pvt Ltd, Rail Vihar Medical College Road, Chargawa, Gorakhpur 273001	Institutional Ethics Committee Rana Hospital, Rana Hospital Pvt. Ltd., Rail Vihar, Medical College Road, Chargawan, Gorakhpur, Uttar Pradesh – 273001. [ECR/1332/Inst/UP/2020]	Dr. Vishal Tripathi

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 Prospective, Randomized, Observer Blind, Parallel, Active Controlled, Multicentre, Non-Inferiority Phase III Study to evaluate the Immunogenicity and Safety of Live Attenuated Varicella Vaccine of Novo Medi Sciences Pvt. Ltd. compared to a marketed Varicella Vaccine in Healthy Subjects” [Protocol no. CRNI/CTP/013, Version no.:1.0 dated 20.03.2023].
- 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:

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