File No: BIO/CT/21/000048
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002
Dated: 25-Mar-2022

To,

M/s Joint Force Pharamchem Pvt. Ltd.,
504, Part B, Samarth Commercial Premisesco. So. Ltd
5th Floor, Survey No.27/E, Hissa No. 1(PT),CTS No.337/1,
Mumbai city Govandi (India) – 400088.

Subject: Permission for conducting a Phase III clinical trial titled "Prospective, Multicentre, Randomized, Double-Blind, Parallel-Group, Phase III Study Comparing Immunogenicity, Safety, and Tolerability of Single Dose of Hepatitis A (Live) Vaccine, Freeze-dried versus BiovacTM-A (Freeze-dried Live Attenuated Hepatitis A Vaccine) in Healthy Indian Children" [Protocol Number: JFP/HAV/CT-01/21, Version no. 1.1, Dated 25.08.2021]- regarding.

Reference: Your Application No. BIO/CT04/FF/2021/25002 dated 16-April-2021 on the subject mentioned above.

Sir,

Please refer to your application no. No. BIO/CT04/FF/2021/25002 dated 16-April-2021, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase III study in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

VENUGOPAL G SOMANI

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

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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 Mr. Errol Silvapinto of M/s Joint Force Pharamchem Pvt. Ltd.,, 504, Part B,Samarth Commercial Premisesco.So.Ltd 5th Floor,Survey No.27/E,Hissa No.1(PT),CTS No.337/1,Mumbai city Govandi (India) - 400088 Telephone No.: 2242290226,42153852 FAX: 2225559434 E-Mail: ERROL@JOINTFORCEPHARMA.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol Number: JFP/HAV/CT-01/21, Version no. 1.1, Dated 25.08.2021 in the below mentioned clinical trial sites.

CT No.: CT- 06/2022

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: 25-Mar-2022

VENUGOPAL G SOMANI

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(Dr. V. G. Somani)
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:	Hepatitis A (Live) Vaccine, Freeze-Dried	
Therapeutic class:	Vaccine	
Dosage form:	Injection through Subcutaneous route at the upper arm deltoid region	
Composition:	Each dose of 1.0 mL of vaccine contains:	
	Name of ingredients	**Quantity**
	Live attenuated Hepatitis A Virus	NLT 6.5 log $CCID_{50}$ of live Hepatitis A virus
	Gelatin	2.5mg
	Trehalose	35mg
	Glycine	5mg
	Dextran	5mg
	Sterile Water for Injection	1ml
Indication:	For active immunization against infection caused by Hepatitis A Virus	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Vijay Vallabh Hospital and Medical Research Centre, Tirupati Nagar Rd, beside Banjara Hotel, Phase 1, Tirupati Nagar, Virar (West), Palghar, 401303, Maharashtra, India.	Institutional Ethics Committee of Vijay Vallabh Hospital and Medical Research Centre, Vijay Vallabh Hospital and Medical Research Centre No-406, Fourth Floor, Plot No423, Tirupati Nagar, Phase 1, Bolinj, Virar (West), Palghar, 401303, Maharashtra, India. [ECR/880/Inst/MH/2017/RR-20]	Dr. Gaurav Sharma
2	Cheluvamba Hospital, MMC & RI, Opp Mysore Medical College, KR Hospital Compound, Irwin Rd, Devraj Mohalla, Mysuru, 570001, Karnataka, India	IEC-MMC and RI and Associated Hospital, Mysore Medical College and Research Institute, Mysore Medical College and Research Institute, Irwin Road, Mysuru, 570001, Karnataka, India. [ECR/134/Inst/KA/2013/RR-19]	Dr. Pradeep Nanjappa
3	College of Medicine & JNM Hospital, Kolkata JNM Hospital quarter E/88, Kalyani, Nadia, 741235, West Bengal, India.	Institutional Ethics Committee College of Medicine and JNM Hospital College of Medicine and JNM Hospital West Bengal University of Health Sciences Kalyani, Nadia, 741235, West Bengal, India. [ECR/674/Inst/WB/2014/RR-17]	Dr. Biplab Tudu
4	Shubham Sudbhawna Superspeciality Hospital, Bhogabir, Lanka, Varanasi, 221005, Uttar Pradesh, India.	Institutional Ethics Committee, Shubham Sudbhawana Superspeciality Hospital, B 31/80, 23B - Bhogabeer, Lanka, Varanasi, 221005, Uttar Pradesh, India. [ECR/667/Inst/UP/2014/RR-20]	Dr. Madhukar Pandey

5	Rajendra Institute of Medical Sciences, Rims Cir, Indraprasth Colony, Bariatu, Ranchi, 834009, Jharkhand, India.	Institutional Ethics Committee, Rajendra Institute of Medical Sciences, Rims Cir, Indraprasth Colony, Bariatu, Ranchi, 834009, Jharkhand, India. [ECR/769/Inst/JH/2015/RR-18]	Dr. Minni Rani Akhouri

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

1. The Phase III clinical trial should be conducted as per protocol titled "Prospective, Multicentre, Randomized, Double-Blind, Parallel-Group, Phase III Study Comparing Immunogenicity, Safety, and Tolerability of Single Dose of Hepatitis A (Live) Vaccine, Freeze-dried versus BiovacTM-A (Freeze-dried Live Attenuated Hepatitis A Vaccine) in Healthy Indian Children" [Protocol Number: JFP/HAV/CT-01/21, Version no. 1.1, Dated 25.08.2021].
2. The firm is required to ensure the limits of impurities as per Chinese Pharmacopoeial requirements.
3. Firm is required to submit the analytical validation report.
4. Firm is required to constitute a DSMB to review the safety data.
5. Firm is required to submit copy of the Insurance Certificate of proposed Phase III clinical trial.
6. 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.
7. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 25-Mar-2022

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