



सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/21/000129

To,

M/s Bharat Serums And Vaccines Limited,
17th Floor, Hoechst House, Nariman Point
Mumbai (India) – 400021.

Sir,

With reference to your application No. GCT/CT04/FF/2021/28392 (GCT/129/21) dated 06-10-2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Randomized, Parallel-group Multi- Center, Assessor- blind Phase 3 Study to compare the Efficacy, Safety and Ease of use of Two Follicle Stimulating Hormone- Human Recombinant (r-hFSH) 900 IU (66.0 µg)/1.5 mL Solution for Injection in Prefilled Pen (Foligraf®- Manufactured by BSV and Gonal-f® Manufactured by Merck Serono) in Subjects Undergoing Controlled Ovarian Stimulation for Assisted Reproductive Technology [REFRESH]”, Protocol Number: BSV_rhFSH_20_09 Protocol Version 1.1 dated 21-September-2021** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

- (i) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;
- (ii) where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:
Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:
Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;
- (iii) in case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

File No. CT/129/21-DCG(I)

- (iv) the Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
- (v) clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;
- (vi) clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;
- (vii) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (viii) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;
- (ix) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;
- (x) any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;
- (xi) in case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;
- (xii) in case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;
- (xiii) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;
- (xiv) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
- (xv) the laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xvi) the Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;
- (xvii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

File No. CT/129/21-DCG(I)

- (xviii) Merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;
- (xix) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

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

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**

1. The Central Licensing Authority hereby permits **M/s Bharat Serums And Vaccines Limited, 17th Floor, Hoechst House, Nariman Point Mumbai (India) – 400021** to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: BSV_rhFSH_20_09 Protocol Version 1.1 dated 21-September-2021** in the below mentioned clinical trial sites [As per Annexure].-

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

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Follicle Stimulating Hormone –Human Recombinant (r-hFSH) 900 IU (66.0 g) / 1.5mL Solution for Injection in Prefilled Pen
Therapeutic class:	Hormones and Antihormones
Dosage form:	Solution for Injection in Prefilled Pen
Composition:	Water for Injection = 1.5000 q.s. B.P.,I.P.,U.S.P. Inactive Phosphoric acid = 0.0000 Not Applicable (NA) B.P.,I.P. Inactive Meta-cresol = 4.5000 milligram (mg) B.P. Inactive Polysorbate 20 (Tween 20) = 0.6000 milligram (mg) B.P.,I.P. Inactive L-Methionine = 0.6000 milligram (mg) B.P. Inactive Sucrose = 30.0000 milligram (mg) B.P.,I.P. Inactive Mannitol = 90.0000 milligram (mg) B.P.,I.P. Inactive Disodium hydrogen phosphate anhydrous = 4.2600 milligram (mg)

File No. CT/129/21-DCG(I)

	B.P. Inactive Follicle Stimulating Hormone concentrated solution (Follitropin concentrated solution)(r-DNA origin) = 900.0000 IU I.P. Active Sodium hydroxide = 0.0000 Not Applicable (NA) B.P.,I.P. Inactive
Indications:	Anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with clomiphene citrate. Stimulation of multi-follicular development in patients undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilization (IVF), gamete intra-fallopian transfer (GIFT) and Zygote IntraFallopian Transfer (ZIFT)

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Milann, (A Unit of BACC Healthcare Pvt. Ltd.) No. #7, East Park Road, Kumara Park East, Bangalore, Karnataka-560001	IIRRH-BACC Healthcare Institutional Ethics Committee, No. #7, East Park Road, Kumara Park East, Bangalore, Karnataka-560001 ECR/773/Inst/KA/2015/RR-18	Dr. Kamini A Rao
All India Institute of Medical Sciences, Room No. 3090-A, Dept of Obstetrics & Gynaecology, 3 rd Floor, Teaching Block, All India Institute of Medical Sciences, New Delhi-110029, India	Institute Ethics Committee, AIIMS, New Delhi, Room No. 102, First-Floor, Old O.T. Block, AIIMS, Ansari Nagar, New Delhi-110029 ECR/538/Inst/DL/2014/RR-20	Dr. Reeta Mahey