Supplementary File S1. Blank Informed Consent Form

Study title	An open label, balanced, randomized, two-treatment, single-period, single-dose, parallel bioequivalence study of Semaglutide Solution for Injection 0.5 mg of Dr. Reddy's Laboratories Limited, India comparing with Ozempic® (semaglutide) solution for injection in pre-filled pen 0.5 mg of Novo Nordisk Farmacêutica do Brasil Ltda. in healthy adult human subjects under fasting condition.
Project number	AZBE052311
Form number	CL-004
ICF document status	Blank/de-identified copy for journal records
Protocol version/date	Version 1.0 dated 02-JUN-2023
Approving ethics committee	Independent Ethics Committee, #132/1, Bharathi Colony, Anna Nagar West, Chennai - 600040, Tamil Nadu, India; Registration No. ECR/111/Indt/TN/2013/RR-19.
Initial IEC approval date	24-JUN-2023
Participant identifying information	Not included. This blank copy contains no participant names, signatures, initials, dates of birth, addresses, contact details, nominee details, or registration numbers.

De-identification statement

This document is a blank informed consent form prepared for journal record purposes only. It contains the study information, study procedures, risks, confidentiality provisions, compensation and subject-rights information relevant to the study, but does not contain any participant-identifying information. Fields that would normally collect participant names, signatures, initials, dates of birth, addresses, nominee details, contact information, registration numbers, or signature dates have been intentionally omitted.

Important note for journal records

This blank copy is not a signed informed consent form and is not evidence of participation by any individual subject. Written informed consent was obtained from study volunteers before participation according to the approved study procedures and applicable ethical requirements.

1. Invitation to participate

You are being invited to participate in a bioequivalence research study. The purpose of this informed consent form is to explain the study, procedures, possible risks or discomforts, confidentiality protections, compensation arrangements, and your rights as a voluntary participant. You should participate only after you understand the study and all your questions have been answered by the study doctor or study staff.

2. Nature and purpose of the study

The study is designed to compare the pharmacokinetic profile of a test semaglutide injection formulation with the comparator product Ozempic® (semaglutide) injection. The study will assess whether similar blood concentrations and systemic exposure are achieved after administration of a single subcutaneous dose under fasting conditions. The study drug is given for research purposes and not to treat a disease or improve health status in healthy volunteers.

3. Study products

- Test product: Semaglutide Solution for Injection 0.5 mg, 1.34 mg/mL, developed by Dr. Reddy's Laboratories Limited, India.
- Comparator product: Ozempic® (semaglutide) solution for injection in pre-filled pen 0.5 mg of Novo Nordisk Farmacêutica do Brasil Ltda.
- The assigned treatment will be administered as a single subcutaneous injection according to the approved randomization schedule.

4. Expected number of participants and study duration

Approximately 80 healthy adult human volunteers may be enrolled. The study includes screening, check-in, single-dose administration, in-clinic confinement, ambulatory blood-sampling visits, and post-study safety assessment. The total duration from check-in to the final post-dose/post-study assessment is approximately 35 days.

5. Study procedures

- Screening procedures may include medical history, physical examination, vital signs, ECG, clinical laboratory tests, urine testing, serology, alcohol/drug screening, and pregnancy testing for eligible participants where applicable.
- Eligible participants will be admitted to the clinical facility before dosing and will remain confined until approximately 72 hours after dosing.
- Participants will receive one subcutaneous injection in the abdominal region under fasting conditions.
- Standardized meals, activity restrictions, posture restrictions, and prohibited substances/medications will apply according to the study protocol.
- Participants will return for ambulatory blood-sampling visits after discharge from the clinical facility.

6. Blood sampling schedule

A total of 31 pharmacokinetic blood samples of approximately 4 mL each may be collected at pre-dose and at the following post-dose time points: 1, 2, 4, 8, 12, 16, 24, 26, 28, 30, 32, 34, 36, 40, 44, 48, 52, 56, 60, 64, 72, 84, 96, 120, 168, 240, 312, 480, 648, and 816 hours. Samples up to 72 hours are collected during in-clinic confinement, and later samples are collected during ambulatory visits. The total blood volume collected will remain within protocol-defined limits.

The first 22 blood samples may be collected during in-clinic confinement, and the remaining 9 samples may be collected during ambulatory visits. The initial samples may be collected through an indwelling cannula placed in a forearm vein, while later ambulatory samples may be collected by direct venous puncture. Normal saline may be used to maintain cannula patency, and an initial discard sample may be collected when required before obtaining the pharmacokinetic sample. The total blood volume collected during the study will not exceed approximately 149.0 mL for male participants and 151.0 mL for female participants, inclusive of applicable pregnancy testing.

7. Fasting and study restrictions

- Participants will fast for at least 8 hours before dosing and for at least 4 hours after dosing.
- Participants should avoid alcohol, tobacco-containing products, caffeine/xanthine-containing beverages, grapefruit products, citrus products, and non-permitted medications as instructed by study personnel.
- Participants should not perform strenuous activity during the study period and should comply with all protocol-defined restrictions.

8. Possible risks and discomforts

Participation may involve risks and discomforts, including adverse events related to semaglutide exposure, injection-site reactions, nausea, vomiting, diarrhoea, headache, dizziness, hypoglycaemia, abdominal symptoms, allergic reactions, discomfort from repeated blood draws, bruising, pain, infection at venipuncture site, or other unforeseen risks. Participants should immediately inform the study doctor or study staff about any discomfort, illness, or adverse event.

9. Safety monitoring

Safety will be monitored through clinical observation, adverse event assessment, vital signs, blood glucose monitoring, physical examination, ECG where applicable, laboratory tests, urine analysis, and post-study safety assessment. Medical care will be provided for study-related adverse events according to applicable regulations and study procedures.

10. Benefits

Healthy volunteers are not expected to receive direct medical benefit from participation. The study may contribute to scientific knowledge regarding pharmacokinetic comparability of semaglutide formulations and may support the development of alternative formulations if bioequivalence is demonstrated.

11. Confidentiality and data protection

Personal health information collected during the actual study is handled confidentially and used for clinical research, quality review, regulatory submission, and scientific reporting. Study data may be reviewed by the investigator, sponsor or sponsor representatives, ethics committee, auditors, and regulatory authorities. Published or submitted results will not identify individual participants.

12. Voluntary participation and right to withdraw

Participation in the study is voluntary. A participant may refuse to participate or may withdraw from the study at any time without penalty or loss of entitled medical care or legal rights. If a participant withdraws, information already collected may continue to be used as permitted by applicable law and approved study procedures.

13. Termination of participation

A participant's involvement in the study may be terminated if the participant withdraws consent, develops an adverse event requiring discontinuation, is found to have entered the study in violation of the protocol, experiences a significant protocol violation, requires medication that may interfere with study drug pharmacokinetics, fails to attend required study visits, shows misconduct or non-cooperation affecting study conduct, or if the investigator determines that discontinuation is in the participant's best interest. If participation is terminated, required medical care will be provided when clinically indicated, and information already collected may continue to be used as permitted by applicable law and approved study procedures.

14. Compensation and medical care for study-related injury

Participants may receive compensation for time and inconvenience according to the approved study procedures. If a study-related injury occurs, medical management and compensation will be handled according to applicable regulatory requirements and approved study procedures.

15. New information

Any new information that may affect a participant's willingness to continue participation will be communicated to the participant, and the participant may decide whether to continue or withdraw from the study.

16. Questions and contacts

Participants may contact the study investigator or study staff for questions about the study, procedures, safety concerns, or study-related injury. Participants may also contact the ethics committee for questions about participant rights or ethical aspects of the study. Contact details are not displayed in this de-identified blank copy prepared for journal records.

17. Participant authorization and declaration

This section would normally document the participant's confirmation that the study has been explained, questions have been answered, participation is voluntary, and permission is given for collection and use of study data. Participant names, initials, signatures, dates, addresses, nominee details, and any other identifying fields have been intentionally omitted from this blank journal-record copy.

18. Investigator declaration

This section would normally document the investigator's confirmation that relevant study information was explained to the participant before consent was obtained. Investigator and participant signature fields have been omitted from this blank de-identified copy for journal records.