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Research Article

Bridging Innovation and Access: Randomized, Single-Dose, Open-Label, Parallel-Group Bioequivalence Study of Generic and Innovator Injection Semaglutide in India

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Abstract: Semaglutide, a long-acting Glucagon-Like Peptide-1 (GLP-1) receptor agonist, is effective in improving glycemic control, reducing body weight, and lowering cardiovascular risk in Type 2 Diabetes Mellitus (T2DM). Limited accessibility of the innovator formulation underscores the need for bioequivalent generic alternatives. To assess the pharmacokinetic bioequivalence of a synthetic Semaglutide Injection (2 mg/1.5 mL) developed by Alkem Laboratories Ltd., India, compared with the innovator product under fasting conditions in healthy adults. This randomized, open-label, single-dose, two-arm, parallel-group bioequivalence study enrolled 80 healthy male and female volunteers (18–45 years). Participants received a single 0.5 mg subcutaneous dose of either the test or reference formulation. Plasma Semaglutide concentrations were measured up to 816 hours post-dose using a validated LC-MS/MS method. Pharmacokinetic parameters (Cmax, AUC_{0-t}, $AUC_{0-\infty}$) were derived by non-compartmental analysis and statistically compared using ANOVA on log-transformed data. Bioequivalence was concluded if 90% Confidence Intervals (CI) for geometric mean ratios were within 80.00–125.00%. Seventy-five subjects completed the study and were included in the analysis. The geometric mean ratios (90% CI) were 94.60% (88.46–101.17%) for Cmax, 96.70% (91.13–102.60%) for AUC_{0-t}, and 96.00% (89.76–102.67%) for $AUC_{0-\infty}$, all within regulatory bioequivalence limits. Concentration–time profiles were comparable between formulations, with no statistically significant differences ($p>0.05$). Both products were well tolerated, and no serious adverse events occurred. The synthetic Semaglutide Injection was pharmacokinetically bioequivalent to the innovator product and demonstrated good tolerability. These findings support its use as a cost-effective alternative that may enhance access to GLP-1-based therapy in resource-limited settings.

Keywords: Semaglutide, Bioequivalence, Generic Injectable, Pharmacokinetics, Type 2 Diabetes Mellitus

Introduction

As a glucagon-like peptide-1 receptor agonist, semaglutide has recently established itself as a key pharmacological agent in the therapeutic landscape of type 2 diabetes mellitus. Its pharmacological actions include stimulation of insulin secretion in a glucose-dependent manner, suppression of glucagon release, and delayed gastric emptying. By engaging multiple complementary pathways, semaglutide enhances glycaemic regulation and leads to clinically significant weight reduction (Drucker, 2018; Nauck and Meier, 2018). Its once-weekly dosing offers an advantage over short-acting GLP-1 agents, improving adherence and treatment consistency (Davies et al., 2021). The SUSTAIN clinical trial program has shown that Semaglutide effectively reduces HbA1c and body weight with a low risk of hypoglycemia (Pratley et al., 2020). By

engaging multiple complementary pathways, semaglutide enhances glycaemic regulation and leads to clinically significant weight reduction (Marso et al., 2016).

Type 2 diabetes mellitus represents an escalating global health challenge, currently affecting approximately 537 million adults worldwide, with projections indicating an increase to 783 million by the year 2045. (Magliano and Boyko, 2021). India accounts for around 77 million cases, the second-highest worldwide (Anjana and Pradeepa, 2017). The increasing burden of disease highlights the urgent need for therapies that are effective, safe, and economically accessible. The innovator semaglutide developed by Novo Nordisk has set a high standard for efficacy among long-acting glucagon-like peptide one receptor agonists. However, its relatively high cost and restricted availability in resource-limited settings may limit sustained use over the long term (Katz, 2025). With the anticipated expiration of its patent in March 2026 (National Center for Biotechnology Information, 2023), there is a significant opportunity to facilitate the development and introduction of more affordable generic formulations.

For generic approvals, particularly for peptide-based therapies such as semaglutide, regulatory agencies mandate demonstration of bioequivalence to the reference formulation, primarily assessed using pharmacokinetic measures, including maximum plasma concentration (Cmax) and Area Under the Concentration–time curve (AUC) (United States Food and Drug Administration, 2022). Given peptides' sensitivity to formulation and delivery changes, these assessments are particularly critical (European Medicines Agency, 2010).

While prior semaglutide bioequivalence and pharmacokinetic studies have primarily focused on oral formulations or comparative bioavailability between oral and subcutaneous administration (Nielsen et al., 2025; Bouhajib et al., 2025), or on innovator device modifications in clinical trials conducted by Novo Nordisk, limited published data are available on synthetic injectable generic formulations developed in India. This study evaluates the pharmacokinetic bioequivalence of a generic Semaglutide injection (2 mg/1.5 mL, 1.34 mg/mL) developed by Alkem Laboratories Ltd., India, compared with the innovator product in healthy adults under fasting conditions. The findings aim to support regulatory approval and improve access to high-quality, affordable treatment for T2DM.

Materials and Methods

Study Design

This was an open-label, randomized, balanced, single-dose, two-treatment, two-arm, parallel-group bioequivalence. conducted in healthy adult volunteers under fasting conditions. Although the study was open-label, the analytical staff responsible for bioanalysis were blinded to the sequence of administration of the test (T) and reference (R) formulations until completion of the study. A parallel study design was employed in view of the prolonged elimination half-life of semaglutide, which makes a crossover design impractical (Granhall et al., 2019). The study was conducted in compliance with Good Clinical Practice (GCP), the Declaration of Helsinki, and applicable regulatory guidelines. Ethical approval was obtained from an Independent Ethics Committee (IEC Reg. No: ECR/1217/Inst/MH/2019), and the study was registered and monitored in accordance with national regulatory requirements.

Study Population

Eighty healthy male and female subjects aged 18–45 years with a body mass index (BMI) of 18.5–25.0 kg/m² were enrolled. Participant eligibility was established following assessment of medical history, physical examination, vital signs, 12-lead electrocardiography, and routine clinical laboratory tests. Written informed consent was obtained from all participants before study enrolment. Major exclusion criteria comprised the presence of any clinically relevant systemic disease, documented hypersensitivity to semaglutide or related agents, involvement in another clinical trial within 90 days preceding dosing, a history of alcohol or substance misuse, active smoking, and pregnancy or breastfeeding among female participants.

Dosing and Sample Collection

Subjects were randomized by computer software to receive a single 0.5 mg subcutaneous dose of either the test product (Semaglutide Injection 2 mg/1.5 mL, Alkem Laboratories Ltd., India) or the reference product (Ozempic® 2 mg/1.5 mL, Novo Nordisk A/S). Following an overnight fasting period of at least 10 hours, dosing was administered subcutaneously in the lower abdomen. The study drug was administered by trained nurses using a standardized subcutaneous injection technique, with injection sites rotated across subjects to minimize local tissue effects and ensure consistent absorption. A total of 31 blood samples (5 mL each) were collected from each subject, including one pre-dose sample (within 1 hour before dosing) and multiple post-dose samples up to 816 hours. Samples after 84 hours were collected on an ambulatory basis, and subjects were discharged after the 72-hour sample. Blood sampling was given priority if it coincided with meals or vital sign assessments.

Bioanalytical Method

Plasma concentrations of semaglutide were quantified in K_2EDTA plasma using a validated liquid chromatography–tandem mass spectrometry (LC-MS/MS) method under Good Laboratory Practice (GLP)

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conditions. Semaglutide-D5 was used as the internal standard. The analytical method demonstrated linearity across a concentration range of 1.011–300.717 ng/mL and complied with regulatory requirements for accuracy, precision, selectivity, and stability.

Sample Size Calculation

Based on literature reports, an intra-subject variability of approximately 28% for the primary pharmacokinetic parameters of semaglutide was assumed for sample size calculation. With an expected T/R ratio of 95.0–105.3%, a significance level of 0.05, power of 80%, and bioequivalence limits of 80.0–125.0%, a total sample size of 68 subjects was estimated to be sufficient for this parallel study to demonstrate bioequivalence between the test and reference formulations under fasting conditions.

Pharmacokinetic and Statistical Analysis

Pharmacokinetic variables were derived using non-compartmental analysis performed with Phoenix® WinNonlin® software. Primary parameters included maximum plasma concentration (Cmax), area under the plasma concentration–time curve from time zero to the last measurable concentration (AUC_{0-t}), and area under the curve extrapolated to infinity ($AUC_{0-\infty}$). The ANOVA model included treatment as a fixed effect applied to the natural log–transformed pharmacokinetic parameters (Cmax, AUC_{0-t}, and $AUC_{0-\infty}$). Bioequivalence was concluded if the 90% confidence intervals (CI) for the geometric mean ratios (test/reference) were within the predefined acceptance range of 80.00–125.00%.

Pharmacokinetic and bioequivalence analyses were conducted on the per-protocol population, including subjects with evaluable PK profiles. Subjects with incomplete PK data or major protocol deviations were excluded from the analysis.

Results

Pharmacokinetic Outcomes

Of the 80 healthy adult subjects enrolled and dosed, 75 completed the study and were included in the pharmacokinetic (PK) and statistical analysis sets, while 5 subjects discontinued due to side effects and withdrawal of consent (Figure 1). Table 1 provides the pharmacokinetic analysis, which confirms bioequivalence between the test (T) and reference (R) formulations, with comparable Cmax, AUC0–t, and AUC0–∞ values. Geometric mean ratios for Cmax, AUC0–t, and AUC0–∞ were 94.60%, 96.70%, and 96.00%, respectively, and their 90% confidence intervals (88.46–101.17%, 91.13–102.60%, and 89.76–102.67%) were fully contained within the 80.00–125.00% regulatory acceptance range, demonstrating equivalence in both rate and extent of absorption.

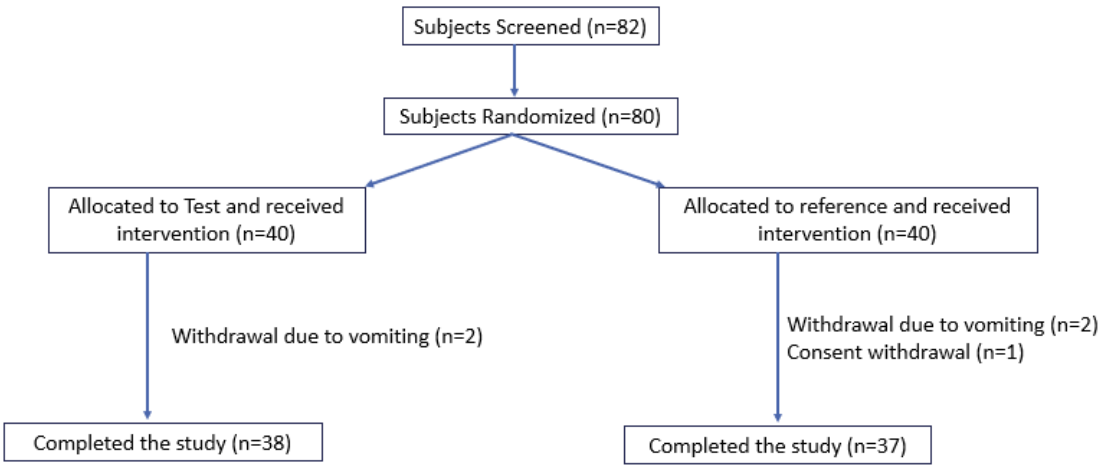

Fig. 1: Subjects' Disposition Flow Chart

Table 1: Geometric Least Squares Means, Ratios, 90% Confidence Intervals, Power, and ISCV for Pharmacokinetic Parameters (Cmax, AUC0-t, and AUC0-∞) of Semaglutide (N = 75)

Parameter	Geometric LSM (Treatment T)	Geometric LSM (Treatment R)	Geometric Mean Ratio (90% CI) (%) T vs R	Inter CV %
Cmax (ng/mL)	72.340	76.467	94.60 (88.46–101.17)	17.58
AUC0-t (ng·hr/mL)	18407.926	19036.842	96.70 (91.13–102.60)	15.49
AUC0-∞ (ng·hr/mL)	19132.768	19929.763	96.00 (89.76–102.67)	17.59

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Parameters were analyzed using ANOVA on log-transformed data. Maximum observed plasma concentration (Cmax), area under the plasma concentration–time curve from time zero to the last quantifiable concentration ($AUC_{0–t}$), area under the plasma concentration–time curve extrapolated to infinity ($AUC_{0–\infty}$), and terminal elimination half-life ($t_{½}$).

Plasma Concentration vs Time Profiles

Both formulations exhibited similar PK profiles with gradual absorption to peak levels and slow monoexponential decline. Semi-log plots confirmed overlapping elimination slopes, indicating comparable half-life and elimination kinetics. In Figure 1, each curve represents the arithmetic mean plasma concentration of Semaglutide measured over 816 hours post-dose following a single 0.5 mg subcutaneous injection under fasting conditions. The test and reference formulations exhibited comparable pharmacokinetic profiles, with no meaningful differences observed in their absorption and elimination phases. A near-identical trend was observed in the rise and fall of Semaglutide concentrations between the test and reference formulations over the 816-hour post-dose period. The semi-logarithmic plot highlights the terminal elimination phase of Semaglutide, showing overlapping elimination slopes for both formulations. This confirms similar pharmacokinetic behavior and supports bioequivalence in the extended disposition phase following a single 0.5 mg subcutaneous dose.

This plot further emphasizes the overlap between the two products during the terminal elimination phase, with comparable elimination slopes, supporting similarity in half-life and elimination kinetics (Figs. 2-3).

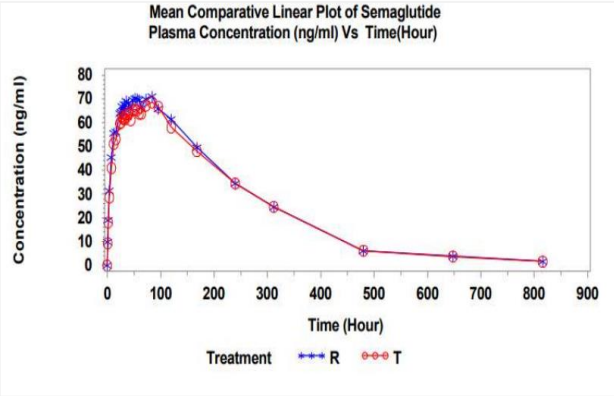

Fig. 2: Linear Plot of Mean Plasma Concentrations of Semaglutide vs. Time for Test Product (T) and Reference Product (R) (N = 75)

Safety and Adverse Event Assessment

Twenty-two TEAEs occurred in 21 subjects (26.25%), with comparable frequency across groups. All were mild (n = 20) or moderate (n = 2); no serious events or deaths occurred. Common TEAEs: injection site reactions (n = 6), nausea (n = 5), headache (n = 4), fatigue/dizziness (n = 3). Fourteen were possibly drug-related, eight unrelated. All resolved without intervention. The safety profile was comparable between formulations (Table 2).

Out of 22 adverse events, 17 adverse events were graded as 'mild,' and 05 adverse events were graded as 'moderate' in intensity, and 22 adverse events were 'possibly' related to the investigational products.

Table 2: Adverse Event Reported Treatment Wise (in Percentage)

Adverse Event	Test Product (T)	Reference Product (R)
Vomiting	02 (5.00%)	03 (7.50%)
Nausea	06 (15.00 %)	03 (7.50 %)
Decrease WBC Count	-	02 (5.00%)
Increase Platelet count	-	02 (5.00%)
Increase RBC count	02 (5.00%)	01 (2.50%)
Decrease Platelet count	-	01 (2.50%)
Total	10 (25.00%)	12 (30.00%)

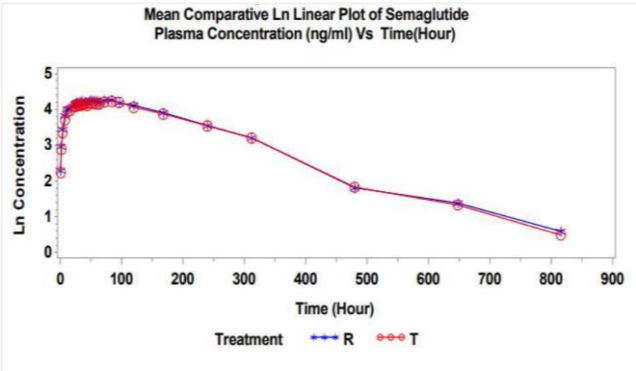

Fig. 3: Ln-Linear Plot of Mean Plasma Concentrations of Semaglutide vs. Time for Test Product (T) and Reference Product (R) (N = 75)

Discussion

This study evaluated the pharmacokinetic bioequivalence of a newly developed generic Semaglutide injection (2 mg/1.5 mL) from Alkem Laboratories Ltd. compared with the innovator product, under fasting conditions in healthy adult volunteers. Analysis of pharmacokinetic data demonstrated that the 90% confidence intervals for the geometric mean ratios of key parameters, including Cmax, $AUC_{0–t}$, and $AUC_{0–\infty}$, fell entirely within the regulatory bioequivalence limits. These findings satisfy the bioequivalence requirements established byf ell within the accepted regulatory range of 80% to 125%, fulfilling bioequivalence criteria set by the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), and India's Central Drugs Standard Control Organization (CDSCO)

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(European Medicines Agency, 2018; United States Food and Drug Administration, 2022).

The pharmacokinetic parameters obtained in the present analysis aligned closely with the data documented in the European Medicines Agency's public assessment report for the reference product. That report documented a Cmax of around 70–75 ng/mL and an $AUC_{0-\infty}$ between 18,000 and 22,000 ng·hr/mL after a 0.5 mg subcutaneous dose (European Medicines Agency, 2016). The terminal elimination half-life in this study (132–135 hours) also aligned closely with findings from the pivotal SUSTAIN-1 and SUSTAIN-6 trials, which reported approximately one week (168 hours), underscoring the reproducibility of Semaglutide's pharmacokinetic profile across populations (Sorli et al., 2017; Marso et al., 2016).

Given the long elimination half-life of Semaglutide, a single-dose, two-treatment, parallel-group design was used to avoid the prolonged washout periods and high dropout risk associated with crossover designs. This approach follows recommendations from international regulatory agencies for drugs with half-lives exceeding 48 hours (United States Food and Drug Administration, 2014; Granhall et al., 2019). The inclusion of 80 healthy adult participants ensured adequate statistical power and reduced the influence of inter-individual variability, which is a critical consideration in parallel study designs. The prolonged post-dose sampling duration of 816 hours allowed comprehensive characterization of both the absorption and elimination phases. Selection of participants within a Normal BMI range (18.5–25.0 kg/m^2) was aligned with the requirements of the Central Drugs Standard Control Organization for generic bioequivalence studies, thereby supporting standardized pharmacokinetic assessment and participant safety. This approach is further supported by population pharmacokinetic data for semaglutide, indicating that its clearance is not significantly influenced by body mass index.

Plasma concentrations of semaglutide were determined using a validated liquid chromatography–tandem mass spectrometry (LC–MS/MS) method employing a stable-isotope labeled internal standard (semaglutide-D5). The analytical procedure was validated for selectivity, sensitivity, accuracy, precision, recovery, and stability in compliance with established regulatory guidelines for bioanalytical method validation (United States Food and Drug Administration, 2022; Guideline, 2022). These findings are consistent with population pharmacokinetic studies demonstrating stable semaglutide exposure and predictable dose proportionality (Lund et al., 2018; Yang and Yang, 2024).

From a clinical perspective, establishing bioequivalence between the test and reference formulations is highly relevant for the Indian healthcare setting. T2DM remains a major public health concern, and GLP-1 receptor agonists like Semaglutide are increasingly recognized for their role in glycemic control and cardiovascular risk reduction. The availability of a domestically manufactured, cost-effective, and therapeutically equivalent alternative to innovator Semaglutide could substantially improve access to long-acting diabetes therapy in both urban and rural communities. From a regulatory and industry perspective, this study provides useful evidence supporting the evaluation of semaglutide formulations. This study is among the early reported bioequivalence evaluations of a generic semaglutide injection in India and contributes to the growing evidence supporting local development of complex peptide-based injectables.

Our study has several strengths. First, this study pioneers Indian bioequivalence evaluation of synthetic semaglutide injection, with robust enrollment yielding high statistical power for all PK parameters, minimizing type II error in a parallel design. Second, extended 816-hour sampling fully characterizes long half-life disposition; validated LC-MS/MS (LLOQ 1.011 ng/mL) ensures precision in the terminal phase ($\%AUC_{0-\infty} <5\%$). Lastly, our study findings align precisely with SUSTAIN reference data, supporting PK/PD predictivity for T2DM outcomes.

Our study has certain limitations. Single-dose administration in healthy volunteers, while standard for BE per CDSCO guidelines, does not capture steady-state pharmacokinetics or pharmacodynamics in T2DM patients, where food effects, renal/hepatic impairment, or obesity may subtly alter exposure, though population PK models predict minimal impact. Parallel-group designs control for long half-life carryover but increase inter-subject variability compared to crossover designs, a concern addressed here with robust enrollment. Lack of multiple-dose or PD endpoints (e.g., insulin secretion) limits direct prediction of clinical outcomes, requiring reliance on established PK/PD relationships from SUSTAIN trials.

Conclusion

The test formulation of Semaglutide Injection (2 mg/1.5 mL) developed by Alkem Laboratories Ltd. is pharmacokinetically bioequivalent to the innovator product when administered under fasting conditions. The study treatments demonstrated good tolerability, with no reports of serious adverse events throughout the study period. This study contributes to the limited published evidence on the bioequivalence evaluation of generic semaglutide injections in India.

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Authors' Contributions

All authors contributed substantially to the conception and design of the study, acquisition and interpretation of data, and critical revision of the manuscript for important intellectual content. Each author participated in drafting or revising the article, approved the final version for publication, and agrees to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part are appropriately investigated and resolved**.**

Ethics

Ethical approval was obtained from an Independent Ethics Committee (IEC Reg. No: ECR/1217/Inst/MH/2019)

Conflict of Interest

Dr. Mayur Mayabhate, Dr. Nitin Kapure, Dr. Akhilesh Sharma, and Dr. Radhakrishna Vaddem are full-time employees of Alkem Laboratories Ltd.

Data Availability Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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