INTERIM STUDY REPORT

IMPROVA TRIAL

A Randomized, Double-Blind, Parallel-Arm Clinical Trial to Assess the Efficacy and Safety of Antox-D Liquid Health Supplement in Participants with Type 2 Diabetes Mellitus

Study Code	MHC/CT/25-26/007
Sponsor	Nutrifeel Health Products Pvt. Ltd.
CRO	Mprex Healthcare Pvt. Ltd.
Protocol Version	2.00 (dated 31st July 2025)
Phase	Phase II Interventional Clinical Trial
Report Date	April 2026 (Interim – Day 90 Data)
Population	n = 102 (Group A: 50; Group B: 52)

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PRIMARY EFFICACY RESULTS

Glycated Hemoglobin (HbA1c)

HbA1c was assessed at Screening and Day 90. Both groups were well-matched at baseline (Group A: 7.48 ± 0.32%; Group B: 7.50 ± 0.33%; p = 0.355). Both groups demonstrated statistically significant reduction, with better numerical reduction observed in Group A.

Timepoint	Group A (Antox-D) Mean ± SD	% Δ	Group B (Placebo) Mean ± SD	% Δ	Between-Group p
Screening	7.48 ± 0.32	—	7.50 ± 0.33	—	0.354
Day 90	6.85 ± 0.36	8.34%	7.30 ± 0.63	2.72%	0.0001

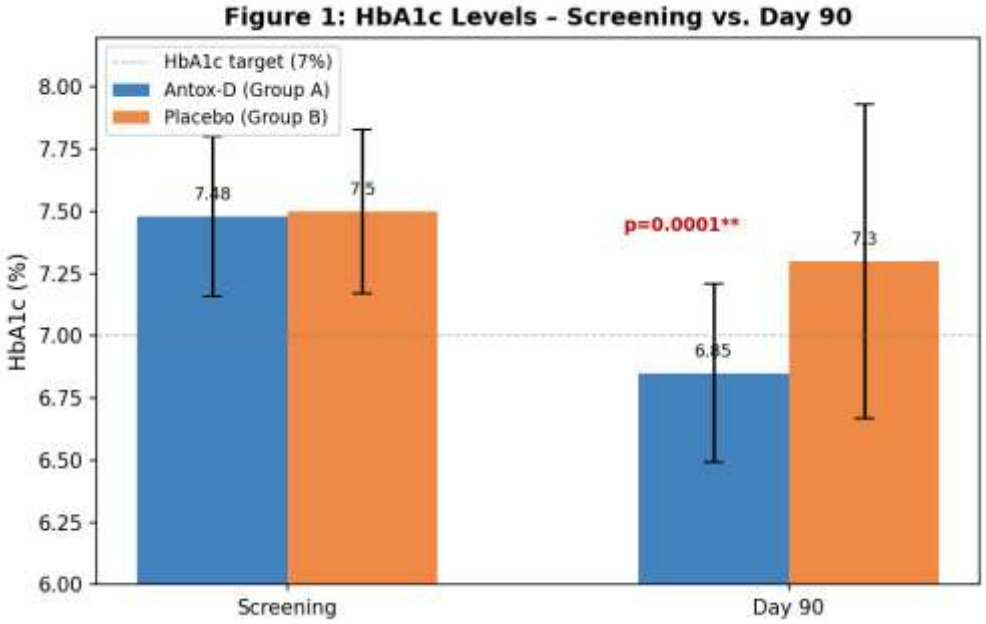

*Figure 1. HbA1c levels at Screening and Day 90. Error bars represent ± SD. ***p < 0.001 between groups at Day 90.*

Fasting Plasma Glucose (FPG)

Fasting plasma glucose was measured at baseline, Day 30, Day 60, and Day 90. A statistically significant between-group difference emerged at Day 90 (Group A: 126.42 ± 22.11 mg/dL vs Group B: 139.15 ± 22.92 mg/dL; p = 0.0015), with the Antox-D group showing a 3.25% reduction from baseline versus a 4.61% increase in the placebo group.

Visit	Group A Mean ± SD	% Δ	Group B Mean ± SD	% Δ	p-value
Baseline	130.67 ± 27.33	—	133.02 ± 30.47	—	0.341
Day 30	131.24 ± 31.02	−0.44%	128.79 ± 25.41	+3.17%	0.155
Day 60	120.04 ± 20.52	−8.13%	130.50 ± 16.71	−1.89%	0.069
Day 90	126.42 ± 22.11	−3.25%	139.15 ± 22.92	+4.61%	0.0015

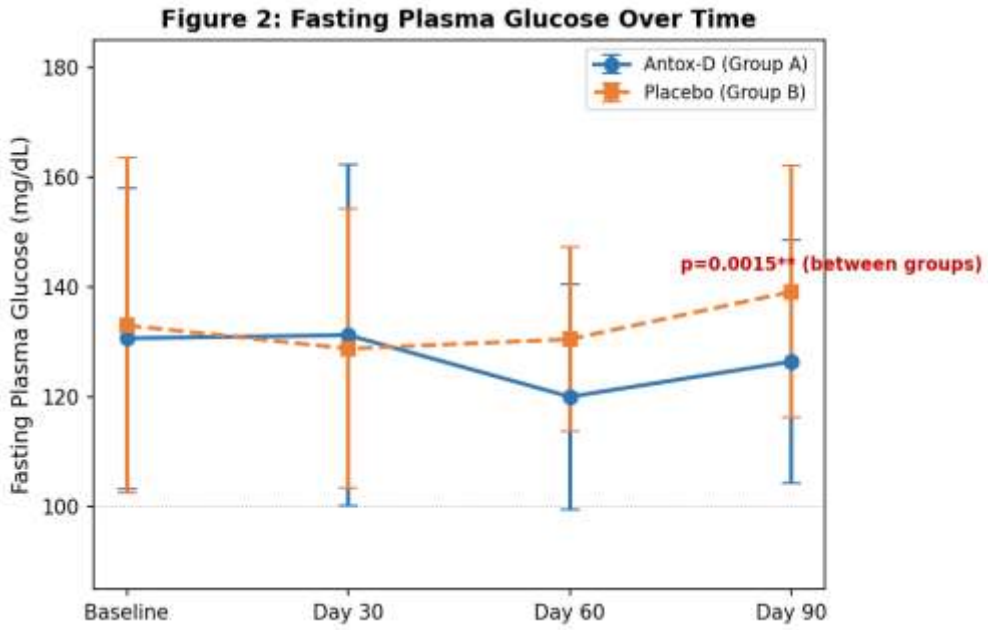

*Figure 2. Fasting Plasma Glucose trend over 90 days. Error bars = ± SD. **p < 0.01 between groups at Day 90.*

Post-Meal Plasma Glucose (PPMG)

Both groups showed clinically meaningful reductions in PPMG across all visits. The Antox-D group achieved a 15.09% reduction at Day 90 compared to 8.00% in the placebo group. While the difference trended toward significance (p = 0.060 at Day 90), within-group significance was strong for Group A at all visits from Day 30 onwards.

Visit	Group A Mean ± SD	% Δ	Group B Mean ± SD	% Δ	p-value
Baseline	196.43 ± 41.15	—	200.63 ± 35.08	—	0.290
Day 30	178.51 ± 30.92	−9.12%	174.34 ± 32.95	−13.10%	0.128
Day 60	164.70 ± 33.51	−16.15%	174.25 ± 22.20	−13.15%	0.176
Day 90	166.80 ± 24.08	−15.09%	184.58 ± 27.24	−8.00%	0.060

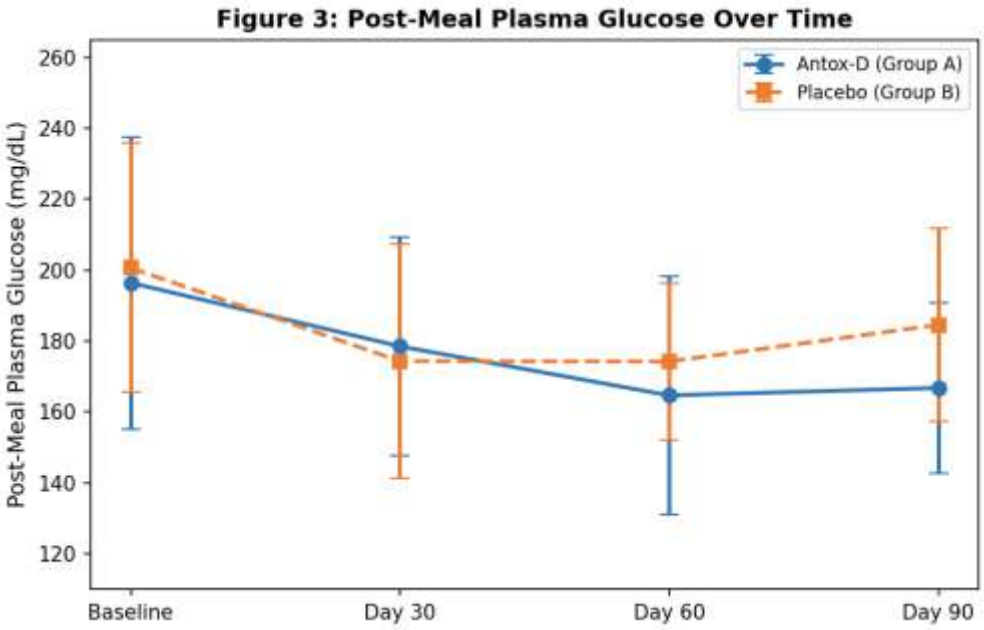

Figure 3. Post-Meal Plasma Glucose over 90 days. Both groups showed progressive reduction, with Group A achieving greater absolute reduction at Day 90. †p < 0.10 (trend).

Insulin Resistance (HOMA-IR)

HOMA-IR was measured at Screening and Day 90. The Antox-D group demonstrated a modest 4.19% decrease in HOMA-IR from 17.30 ± 10.26at screening to16.57 ± 9.06 at day 90, whereas the placebo group showed an unexpected 17.99% increase from 15.79 ± 8.63 at screening to18.63 ± 9.27at day 90. The between-group difference at Day 90 was statistically significant (p = 0.032), suggesting a protective role of Antox-D against worsening insulin resistance over time.

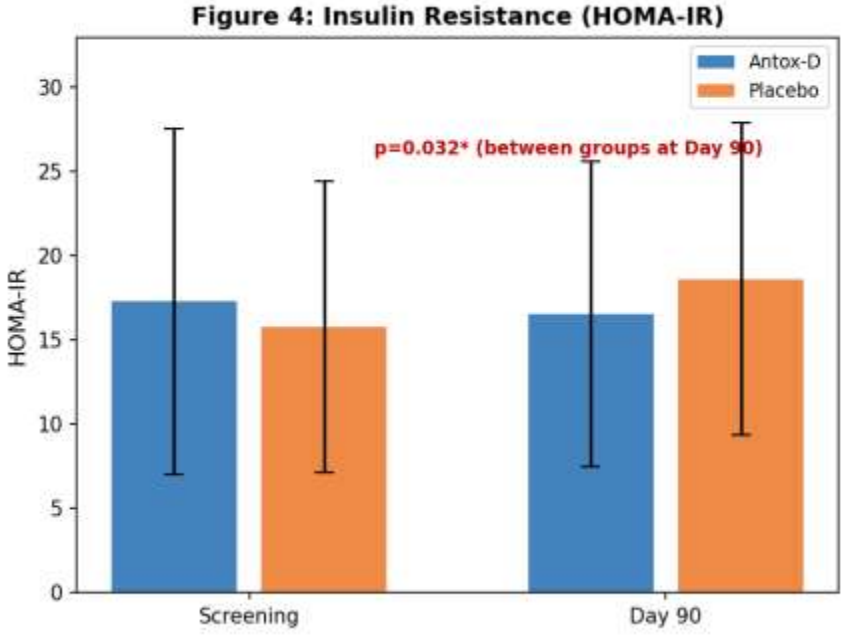

*Figure 4. HOMA-IR at Screening and Day 90. Placebo group shows significant worsening (p = 0.014 within group), while Antox-D group remained stable. *p < 0.05 between groups at Day 90.*

SECONDARY EFFICACY RESULTS

Metabolic Syndrome Z Score (MetS Z Score)

The MetS Z Score is a composite measure of metabolic syndrome severity. The Antox-D group achieved a remarkable 56.45% reduction in MetS Z Score (0.74 → 0.32), compared to only 15.38% in the placebo group (0.72 → 0.61). This between-group difference was statistically significant (p = 0.017).

Visit	Group A Mean ± SD	% Δ	Group B Mean ± SD	% Δ	p-value
Day 1	0.74 ± 0.67	—	0.72 ± 0.62	—	0.412
Day 90	0.32 ± 0.56	−56.45%	0.61 ± 0.58	−15.38%	0.017

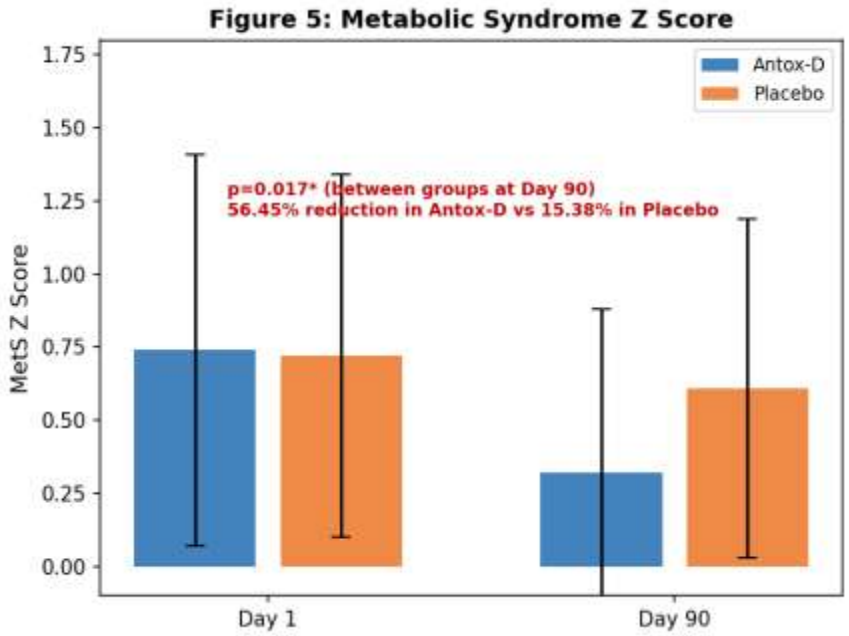

*Figure 5. MetS Z Score at Baseline and Day 90. Antox-D group shows a 56.45% reduction vs 15.38% in placebo. *p = 0.017*

Fasting Insulin

Fasting insulin (µIU/mL) showed a favorable trend in the Antox-D group, with a 7.71% reduction (67.51 → 62.30). The placebo group showed a 5.43% increase (60.35 → 63.63). The between-group difference at Day 90 was statistically significant (p = 0.040).

Visit	Group A Mean ± SD	% Δ	Group B Mean ± SD	% Δ	p-value
Screening	67.51 ± 22.99	—	60.35 ± 20.68	—	0.050
Day 90	62.30 ± 14.91	−7.71%	63.63 ± 15.17	+5.43%	0.040

Fatigue Severity Scale (FSS)

FSS data was stratified by two subgroups: participants with baseline fatigue (FSS ≥ 36) and those without significant fatigue (FSS < 36).

Subgroup with Significant Fatigue (FSS ≥ 36):

The Antox-D group achieved a clinically meaningful 15.98% reduction in FSS at Day 90 (41.21 → 34.62), suggesting resolution of clinically significant fatigue. The placebo group showed only a 5.31% reduction (39.62 → 37.52).The between-group difference at Day 90 was statistically significant (p=0.00001).

Subgroup Without Significant Fatigue (FSS < 36):

Both groups in this subgroup showed modest improvements; the Antox-D group demonstrated a 6.99% reduction (22.48 → 20.90) versus 3.36% in placebo.However,between group difference showed no statistical significance (p=0.43).

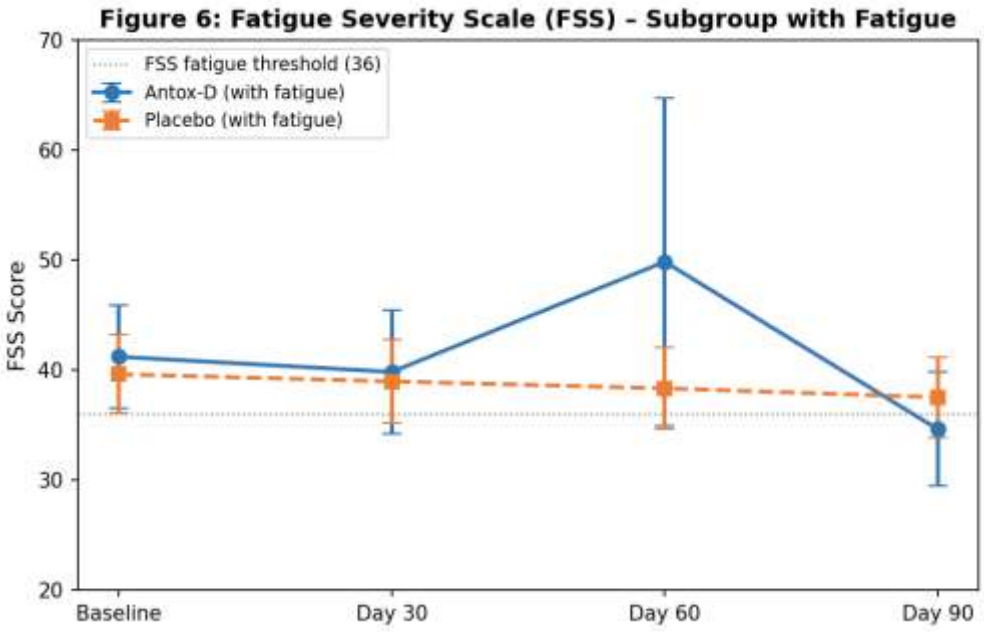

Figure 6. FSS Score over 90 days (participants with significant baseline fatigue). Group A crosses the threshold (< 36) at Day 90, indicating clinically meaningful fatigue resolution.

Visit	Group A Mean ± SD	% Δ	Group B Mean ± SD	% Δ	P value
Baseline	41.21 ± 4.69	—	39.62 ± 3.55	—	0.152
Day 30	39.83 ± 5.63	−3.35%	38.97 ± 3.82	−1.65%	0.126
Day 60	49.83 ± 14.90	−20.92%*	38.34 ± 3.72	−3.22%	0.002
Day 90	34.62 ± 5.17	−15.98%	37.52 ± 3.64	−5.31%	0.001

CONCLUSIONS

Primary Endpoints

- HbA1c reduced by 8.34% in the Antox-D group (7.48% → 6.85%) vs 2.72% in placebo (7.50% → 7.30%); between-group p < 0.0001*— the most compelling finding of this trial.
- HbA1c in the Antox-D group reached 6.85%, approaching the clinical target of < 7%, a level not achieved by the placebo group.
- Fasting Plasma Glucose was significantly lower in Group A at Day 90 (126.42 vs 139.15 mg/dL; p = 0.0015), with a directionally opposite trajectory: Group A decreased 3.25% while Group B increased 4.61%.
- HOMA-IR: The Antox-D group maintained insulin sensitivity (−4.19%) while the placebo group showed significant worsening (+17.99%); between-group p = 0.032.

Secondary Endpoints

- MetS Z Score: Antox-D produced a 56.45% reduction in metabolic syndrome severity vs 15.38% in placebo (p = 0.017) — a large and clinically important finding.
- Fasting Insulin: 7.71% decrease in Group A vs 5.43% increase in Group B (p = 0.040), demonstrating favorable effects on insulin secretion/clearance dynamics.
- Post-Meal Plasma Glucose: Group A achieved a 15.09% reduction vs 8.00% in placebo at Day 90, with a consistent progressive trajectory (p = 0.061, trend).
- Fatigue (FSS): Antox-D participants with significant baseline fatigue achieved a 15.98% FSS reduction at Day 90, crossing the clinical fatigue threshold (< 36), representing a clinically meaningful improvement in patient-reported outcomes.

— END OF INTERIM REPORT —