

A Randomized, Controlled, Double Blind Clinical Study to Evaluate Use of Hydron Alkaline Ionised Water (HAIW) in Healthy Participants with Hyperacidity

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Research Article

Keywords: Alkaline ionized water, HAIW, Packaged drinking water, Hyperacidity, Gastrointestinal symptoms, GSRS, Randomized controlled trial

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A Randomized, Controlled, Double Blind Clinical Study to Evaluate Use of Hydron Alkaline
Ionised Water (HAIW) in Healthy Participants with Hyperacidity

Cohort 1: Hyperacidity

Protocol No. HAIW/ACI&CONS/2024/01, Version 1.0, 7th Oct 2024

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Gastrointestinal symptoms, GSRS, Randomized controlled trial.

ABSTRACT

Background and Objectives:

Alkaline Ionized Water (AIW) is considered the highest level of healthy drinking water worldwide and is widely discussed for its various health benefits. Hydron Alkaline Ionized Water (HAIW) is produced through electrolysis, resulting in a stable pH of approximately 9.5 with a negative Oxidation Reduction Potential (ORP), making it an antioxidant beverage. In addition to its alkalizing effects, HAIW may help neutralize stomach acid and reduce symptoms of acid reflux and heartburn. The objective of this study was to evaluate the efficacy and safety of HAIW in healthy participants with hyperacidity as compared to Packaged Drinking Water (PDW).

Materials and Methods:

A Two Arm, Double Blind, Randomized, Multi-center, Controlled, Prospective clinical study was conducted across five sites in Maharashtra, India. A total of 111 participants were screened in Cohort 1 (hyperacidity). 56 participants were randomized to the HAIW group and 55 to the PDW group. There were 52 completers and 4 dropouts in the HAIW group and 54 completers and 1 dropout in the PDW group. Participants were asked to consume either HAIW or Packaged Drinking Water as and when required (minimum 3L per day) for 30 days. Primary outcome was change in severity of gastrointestinal symptoms assessed on the Gastrointestinal Symptom Rating Scale (GSRS). Secondary outcomes included changes in duration, number of episodes and severity of gastrointestinal symptoms, indigestion and appetite assessment on 0-100 scale, and global assessment of overall change.

Results:

Assessment of 52 participants in the HAIW group and 54 in the PDW group showed significant reduction in all GSRS sub scores with HAIW as compared to PDW at both Day 15 and Day 30. The overall GSRS score reduced from 1.94 ± 0.41 at baseline to 1.55 ± 0.37 at Day 15 and further to 1.20 ± 0.33 at Day 30 in the HAIW group, as compared to 1.98 ± 0.43 at baseline, 1.87 ± 0.42 at Day 15, and 1.82 ± 0.41 at Day 30 in the PDW group ($p < 0.05$). The reflux score reduced from 2.65 ± 0.81 to 1.58 ± 0.54 at Day 30 with HAIW vs. 2.66 ± 0.64 to 2.34 ± 0.56 with PDW ($p < 0.05$). The abdominal pain score reduced from 2.01 ± 0.54 to 1.46 ± 0.43 with HAIW vs. 2.11 ± 0.63 to 1.93 ± 0.52 with PDW ($p < 0.05$). The indigestion score reduced from 2.08 ± 0.84 to 1.41 ± 0.45 with HAIW vs. 2.01 ± 0.70 to 1.88

± 0.67 with PDW ($p < 0.05$). The diarrhoea score reduced from 1.23 ± 0.40 to 1.12 ± 0.34 with HAIW vs. 1.40 ± 0.67 to 1.33 ± 0.55 with PDW ($p < 0.05$). The constipation score reduced from 1.74 ± 0.69 to 1.35 ± 0.30 with HAIW vs. 1.73 ± 0.66 to 1.62 ± 0.63 with PDW ($p < 0.05$). Global assessment by the investigator showed very much improvement in 12 (23.08%), much improvement in 27 (51.92%), and minimal improvement in 13 (25.00%) participants in the HAIW group, while in the PDW group, much improvement was reported in 2 (3.70%), minimal improvement in 28 (51.85%), and no change in 24 (44.44%) participants. None of the 14 adverse events were related to the study products.

Conclusion:

The study concludes that consumption of HAIW showed a significant reduction in symptoms of hyperacidity like acid reflux, pain in abdomen, bloating, burning sensation in the chest and flatulence. These effects were observed within 15 days of starting consuming HAIW and continued further till 30 days. The reduction in these symptoms was found to be significantly better as compared to packaged drinking water. The use of HAIW was found to be safe without causing any adverse effects.

INTRODUCTION

Stomach, a hollow organ of the gastrointestinal tract or digestive system, secretes several types of digestive fluids including HCl (gastric acid), pepsins, mucin and many others. Stomach acid secretion in appropriate amount is essential for the proper digestive process. Hyperacidity is a term generally used when there is excess secretion of hydrochloric acid in the stomach. It can lead to various kinds of diseases such as peptic ulcer disease (PUD) and gastro-esophagus reflux disease (GERD). Eating large or heavy meals, lying down right after a meal, obesity, intake of foods such as citrus, tomato, chocolate, mint, garlic, onions, or spicy or fatty foods, excess intake of alcohol, coffee, or tea, smoking and some medicines such as aspirin, NSAIDs leads to hyperacidity.

Treatment of hyperacidity depends upon its cause. Preventive measures such as lifestyle modification, healthy regular diet, proper sleep and exercise are helpful in the management of hyperacidic conditions. However, pharmacological treatment options include use of antacids (aluminum hydroxide), H₂-receptor antagonists (ranitidine), proton pump inhibitors PPIs (pantoprazole), ulcer coating (sucralfate), prokinetic medication and antiemetic (ondansetron) agents.

Hydron Alkaline Ionized Water (HAIW) is healthy drinking water having various health benefits. It is produced through electrolysis, resulting in a stable pH value in range of 8.5–9.5, and is micro-clustered with a greater concentration of H⁺ ions (Hydrogen ions). Alkaline water has a negative Oxidation Reduction Potential (ORP) which makes it healthy for the body. This helps in restoring blood pH and provides faster hydration, thereby offering several health benefits, including anti-ageing, superior lubrication for muscles and joints, and enhanced immunity. In addition to its alkalizing effects, Hydron Alkaline Ionized Water may help get rid of acidity by neutralizing stomach acid and reducing symptoms of acid reflux and heartburn.

Looking at the activities of Hydron Alkaline Ionized Water, a hypothesis was postulated that it would be useful in the management of hyperacidity. To test the hypothesis, a clinical study titled "A Randomized, Controlled, Double Blind clinical study to evaluate use of Hydron Alkaline Ionized Water (HAIW) in healthy participants with digestive complains hyperacidity and functional constipation" was planned.

MATERIALS AND METHODS

Study Design

A Two Arm, Double Blind, Randomized, Multi-centre, Controlled, Prospective type clinical study was conducted. Participants were randomized in a 1:1 ratio using a computer-generated random allocation list prepared prior to the start of the study. Eligible participants were assigned to either the HAIW group or the PDW group. Both waters were dispensed in identical opaque containers to maintain blinding. The dispensing was done by a third-party staff member not involved in participant assessments. The total study duration was 30 days. There were three visit time points: Screening/Baseline Visit (Day 0), Visit 1 (Day 15 ± 3 days), and End of Study Visit (Day 30 ± 3 days).

The study was conducted across five sites in Maharashtra, India: (1) Shivam Multispecialty Hospital, Solapur-Pune Hwy, Haveli, Maharashtra -NA ; (2) Ayurved Seva Sangh, Ganeshwadi, Panchavati, Nashik 422003 Approval number 720; (3) Nirvikar Ayurveda Hospital, Bhosari, Pune:-NAH/002/25 (4) Seth Govindji Raoji Ayurved Mahavidyalaya and Hospital, Solapur, Maharashtra:-IEC/LTR/SGR/05/2024-25 (5) DY Patil School of Ayurveda, Sector 7, Nerul, Navi Mumbai Approval no:- DYPUSA/25/35. The study was approved by the Institutional Ethics Committees of the respective study sites and registered with CTRI (CTRI/2025/01/079462) on 24/01/2025.

Inclusion Criteria:

Participants that met all of the following criteria were included in the study. Healthy males and females between 18 to 60 years of age (both inclusive) with any of the mild to moderate symptoms that included bloating, feeling of acid reflux, early fullness during a meal, pain or discomfort in the upper abdomen, burning in the upper abdomen, pain/burning in the centre of chest, nausea, vomiting, burping, flatulence, indigestion, and appetite were considered eligible; healthy individuals were defined as those who did not take any medications and did not require continuous medical care and monitoring. Additionally, participants were required to have been suffering from any of the above symptoms for at least the last six months and were willing to follow the procedures as per the study protocol and voluntarily sign an informed consent form.

Exclusion Criteria:

Participants meeting any of the following criteria were excluded from the study. Participants with known tuberculosis, hepatitis B and C, HIV, ischemic heart disease, cancer, kidney failure, or chronic liver diseases were excluded, as were those having jaundice or any other symptom of active hepatitis. Participants who had consumed any other investigational product within 1 month prior to randomization were not eligible, nor were those suffering from any other functional dyspepsia or any other functional gastrointestinal disorder.

Participants with diabetes mellitus and hypertension taking regular medications, pregnant and lactating women, and those with any significant abnormal laboratory parameters were also excluded. Known hypersensitivity to Hydron Alkaline Ionised Water (HAIW) or packaged drinking water was an additional exclusion criterion, along with any other conditions which, in the opinion of the investigators, made the participant unsuitable for enrolment or could interfere with his/her participation in and completion of the study.

Study Interventions

Test Product: Hydron Alkaline Ionized Water (HAIW) was prepared using electrolysis of water with a stable pH of approximately 9.5. HAIW was dispensed using Hydron AIW-ATM, a self-serving automated dispensing machine with a capacity of 500–5,000 LPD and output pH up to 9.5.

Control Product: Packaged Drinking Water (PDW) that is commercially available packaged drinking water.

Participants were asked to consume either HAIW or packaged drinking water as and when required for 30 days (minimum 3L per day). A washout period of 3 days was advised to participants who were on any modern medicine, Ayurvedic, Homeopathic, Unani, Siddha medicines and nutraceuticals for acidity.

Primary and Secondary Outcomes

Primary Outcome:

Change in severity of gastrointestinal symptoms assessed on Gastrointestinal Symptom Rating Scale (GSRS) (original interviewer-administered version) from baseline to end of the study and between the two groups (Time Points: baseline visit, Day 15, Day 30).

Secondary Outcomes:

Secondary outcomes included changes in duration, number of episodes, and severity of symptoms including bloating, feeling of acid reflux, early fullness during a meal, pain or discomfort in the upper abdomen, burning in the upper abdomen, pain/burning in the centre of chest, nausea, vomiting, burping, and flatulence from baseline to follow-up visits on Day 15 and Day 30 and between the two groups, where symptoms were graded on a 0–100 scale with 0 indicating no symptom and 100 indicating extreme symptom, and severity was assessed as mild, moderate, or severe. Changes in indigestion and appetite were also assessed on the same 0–100 scale from baseline to Day 15 and Day 30 and between the two groups. Global assessment for overall change by the investigator and participant at the end of the study was evaluated, along with global assessment of tolerability of the study product by assessing ADRs, vitals, and clinical symptoms by the investigator and participant at the end of the study. Assessment of adverse events was carried out from baseline visit to end of study.

Statistical Methods

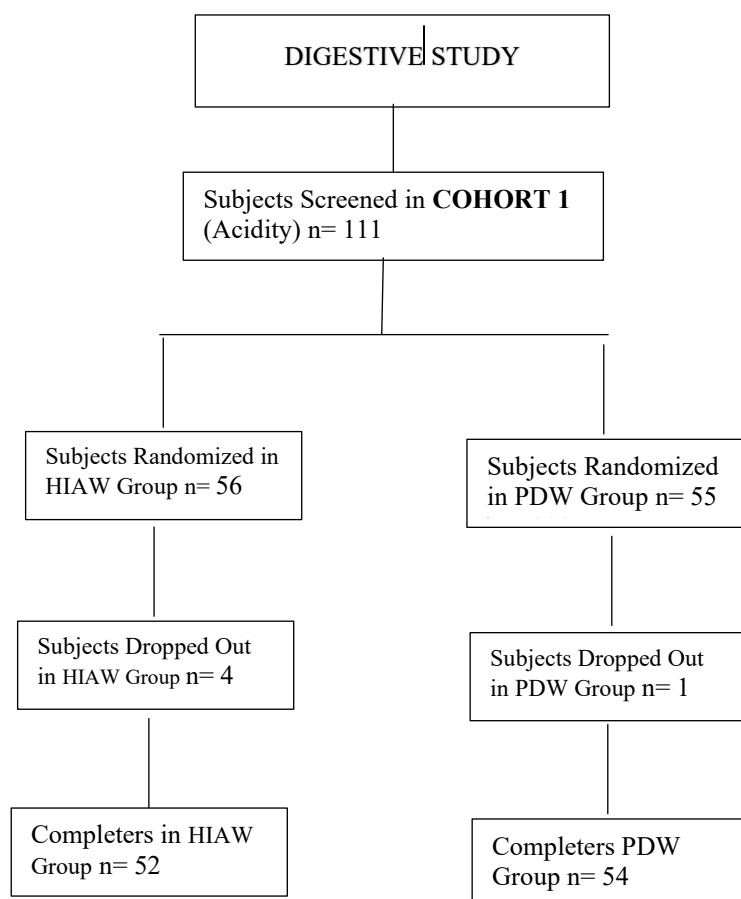
In-house statistician performed statistical analysis using Graphpad statistical software. For the analysis of efficacy variables, data was analyzed from the intent to treat population and per protocol population. The values of the last visit were considered for final analysis for participants who did not complete the study schedule (Last Observation Carry Forward) for intent to treat analysis. Safety Analysis was done on all participants who took at least one dose of study product. Data describing quantitative measures were expressed as mean $\pm$ standard deviation. Qualitative variables were presented as counts and percentage. Comparison of

variables representing categorical data was performed using t test and Chi-square test. All P values were reported based on two-sided significance, and all the statistical tests were interpreted at least up to 5% level of significance. A p-value of <0.05 was considered statistically significant.

RESULTS

Study Population

A total of 111 participants were screened in Cohort 1. 56 participants were randomized in the HAIW group and 55 participants were randomized in the PDW group. There were 52 completers and 4 dropouts in the HAIW group and 54 completers and 1 dropout in the PDW group. A total of 52 participants in the HAIW group and 54 participants in the PDW group completed the study and were considered for assessment.



Baseline Demography

The average age of participants in HIAW group was 36.44 ± 9.08 years while in PDW group it was 35.57 ± 10.91 . There were 23 males (44.23%) and 29 females (55.77%) in HIAW group while in the PDW group there were 22 (40.74%) males and 32 (59.26%) female participants. The average weight and BMI of participants in HIAW group was 62.88 ± 10.86 Kg and 23.48 ± 3.79 Kg/m² respectively while in the PDW group it was 60.88 ± 10.48 Kg and 22.71 ± 3.65 Kg/m² respectively. Non-significant difference was observed between the two groups on all baseline demography parameters. Key characteristics are summarized in Table 1.

Table 1: Assessment of Baseline Demography

Parameters	HIAW group (n = 52)	PDW group (n = 54)
Age (in Years)	36.44 ± 9.08	35.57 ± 10.91
Males	23 (44.23%)	22 (40.74%)
Females	29 (55.77%)	32 (59.26%)
Weight (in kgs)	62.88 ± 10.86	60.88 ± 10.48
BMI (in Kg/m ²)	23.48 ± 3.79	22.71 ± 3.65
p value (Between)	$p > 0.05$ (NS) for all parameters	

Primary Efficacy Parameters

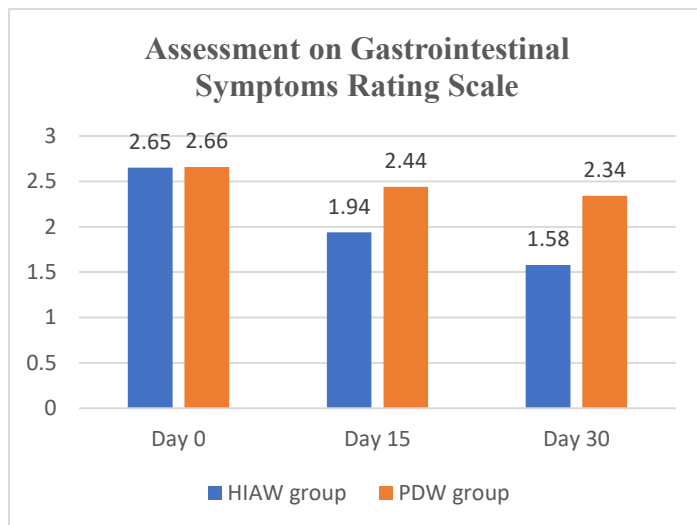
A) Assessment on Gastrointestinal Symptoms Rating Scale (GSRS):

1) Reflux Score: The GSRS, reflux score at baseline visit in HIAW group was 2.65 ± 0.81 which reduced significantly to 1.94 ± 0.66 at the end of 15 days and further to 1.58 ± 0.54 at the end of 30 days. PDW group as well there was a significant reduction in the reflux score from baseline score of 2.66 ± 0.64 to 2.44 ± 0.59 at the end of 15 days and 2.34 ± 0.56 at the end of 30 days. Analysis between the groups showed significant difference with HIAW group showing better reduction in reflux as compared to PDW group at both day 15 and day 30.

Table 2: Assessment on Gastrointestinal Symptoms Rating Scale

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean ± SD	2.65 ± 0.81	1.94 ± 0.66	1.58 ± 0.54	2.66 ± 0.64	2.44 ± 0.59	2.34 ± 0.56
p value (Within group)	-	0.00001 (S)	0.00001 (S)	-	0.00006 (S)	0.00001 (S)
p value (Between groups)	$p = 0.4900$ (NS) Day 0, $p = 0.00003$ (S) Day 15 & $p = 0.00001$ (S) Day 30					

Graph 1: - Assessment on Gastrointestinal Symptoms Rating Scale



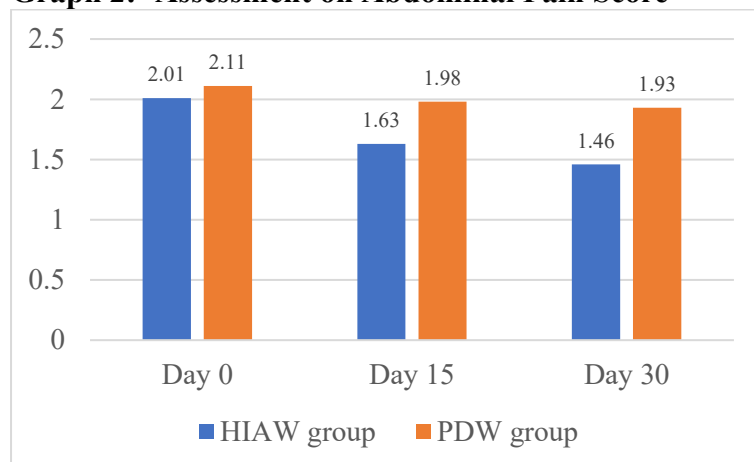
2) Abdominal Pain Score:

The GSRS, Abdominal pain score reduced significantly from a baseline score of 2.01 ± 0.54 to 1.63 ± 0.53 at the end of 15 days and further to 1.46 ± 0.43 at the end of 30 days in HIAW group, similarly in PDW group the score reduced significantly from baseline score of 2.11 ± 0.63 to a score of 1.98 ± 0.48 at the end of 15 days. At the end of 30 days the score reduced significantly to 1.93 ± 0.52 in this group. Assessment between the groups showed a significantly better reduction in abdominal pain score in HIAW group as compared to PDW group at both day 15 and day 30.

Table 3: Assessment on Abdominal Pain Score

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean $\pm$ STDEV	2.01 ± 0.54	1.63 ± 0.53	1.46 ± 0.43	2.11 ± 0.63	1.98 ± 0.48	1.93 ± 0.52
p value (Within)	-	*0.00001 (S)	*0.00001 (S)	-	*0.0062 (S)	*0.0043 (S)
p value (Between)	p = **0.1975 (NS) Day 0, p = *0.00025 (S) Day 15 & p = *0.00001 (S) Day 30					

Graph 2:- Assessment on Abdominal Pain Score



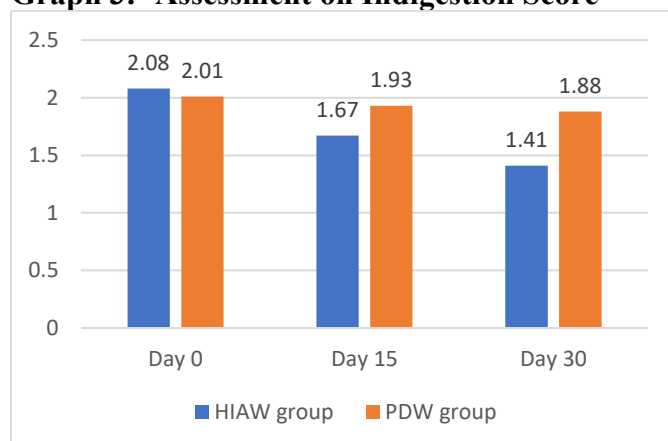
3) Indigestion Score:

The GSRS, indigestion score at baseline visit in HIAW group was 2.08 ± 0.84 which reduced significantly to 1.67 ± 0.62 at the end of 15 days and further to 1.41 ± 0.45 at the end of 30 days. In PDW group as well there was a significant reduction in the indigestion score from baseline score of 2.01 ± 0.70 to 1.93 ± 0.69 at the end of 15 days and 1.88 ± 0.67 at the end of 30 days. Analysis between the groups showed significant difference with HIAW group showing better reduction in indigestion as compared to PDW group at both day 15 and day 30.

Table 4: Assessment on Indigestion Score

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean $\pm$ STDEV	2.08 $\pm$ 0.84	1.67 $\pm$ 0.62	1.41 $\pm$ 0.45	2.01 $\pm$ 0.70	1.93 $\pm$ 0.69	1.88 $\pm$ 0.67
p value (Within)	-	*0.00001 (S)	*0.00001 (S)	-	*0.0054 (S)	*0.0006 (S)
p value (Between)	p = **0.3150 (NS) Day 0, p = *0.0232 (S) Day 15 & p = *0.00002 (S) Day 30					

Graph 3:- Assessment on Indigestion Score



4) Diarrhoea Score:

The GSRS, Diarrhoea score showed significant change from a baseline score of 1.23 ± 0.40 to 1.17 ± 0.40 at the end of 15 days and further to 1.12 ± 0.34 at the end of 30 days in HIAW group, while in PDW group also the score reduced significantly from baseline score of 1.40 ± 0.67 to a score of 1.35 ± 0.58 at the end of 15 days and to a score of 1.33 ± 0.55 at the end of 30 days. Analysis between the groups showed significant difference with HIAW group showing better reduction in reflux as compared to PDW group at both day 15 and day 30.

Table 5: Assessment on Diarrhoea Score

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean $\pm$ STDEV	1.23 ± 0.40	1.17 ± 0.40	1.12 ± 0.34	1.40 ± 0.67	1.35 ± 0.58	1.33 ± 0.55
p value (Within)	-	*0.0496 (S)	*0.0056 (S)	-	*0.0444 (S)	*0.0148 (S)
P value (Between)	p = **0.0661 (NS) Day 0, p = *0.0336 (S) Day 15 & p = *0.0117 (S) Day 30					

5) Constipation Score

The GSRS, constipation score at baseline visit in HIAW group was 1.74 ± 0.69 which reduced significantly to 1.35 ± 0.44 at the end of 15 days and further to 1.35 ± 0.30 at the end of 30 days. In PDW group as well there was a significant reduction in the constipation score from baseline score of 1.73 ± 0.66 to 1.65 ± 0.64 at the end of 15 days and 1.62 ± 0.63 at the end of 30 days. Analysis between the groups showed significant difference with HIAW group showing better reduction in constipation score as compared to PDW group at both day 15 and day 30.

Table 6: Assessment on Constipation Score

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean $\pm$ STDEV	1.74 ± 0.69	1.35 ± 0.44	1.35 ± 0.30	1.73 ± 0.66	1.65 ± 0.64	1.62 ± 0.63
p value (Within)	-	*0.00001 (S)	*0.00001 (S)	-	*0.0089 (S)	*0.0042 (S)
p value (Between)	p = **0.4536 (NS) Day 0, p = *0.0025 (S) Day 15 & p = *0.00001 (S) Day 30					

6) GSRS Score:

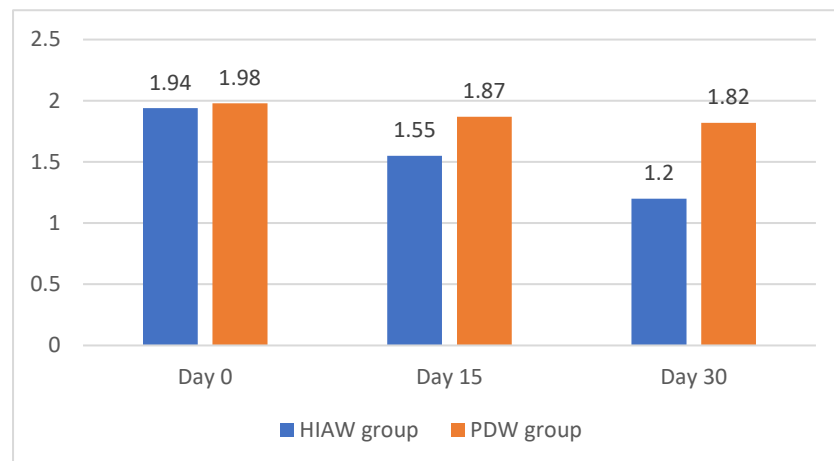
Overall GSRS score reduced significantly from a baseline score of 1.94 ± 0.41 to 1.55 ± 0.37 at the end of 15 days and further to 1.20 ± 0.33 at the end of 30 days in HIAW group, while in

PDW group the score reduced from baseline score of 1.98 ± 0.43 to a score of 1.87 ± 0.42 at the end of 15 days and to a score of 1.82 ± 0.41 at the end of 30 days, showing significant reduction at both visits. Analysis between the groups showed significant reduction in overall GSRS score in HIAW group compared to PDW group.

Table 7: Assessment on GSRS Score

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean $\pm$ STDEV	1.94 $\pm$ 0.41	1.55 $\pm$ 0.37	1.20 $\pm$ 0.33	1.98 $\pm$ 0.43	1.87 $\pm$ 0.42	1.82 $\pm$ 0.41
p value (Within)	-	*0.00001 (S)	*0.00001 (S)	-	*0.00001 (S)	*0.00001 (S)
p value (Between)	p = **0.3352 (NS) Day 0, p = *0.00003 (S) Day 15 & p = *0.00001 (S) Day 30					

Graph 4:- Assessment on GSRS Score



Secondary Efficacy Parameters

A) Assessment of Duration, Number of Episodes and Severity of GI Symptoms:

1) Bloating: In HIAW group amongst the 52 participants there were an average of 0.77 ± 0.76 episodes of bloating while the same was observed to be 1.39 ± 10.4 in PDW group amongst 54 participants, showing a significantly lesser no of episodes of bloating in HIAW group as compared to PDW group. Similarly, the average duration of these episodes was 15.90 ± 12.18 minutes in HIAW group while in PDW group it was observed to be 28.50 ± 18.06 minutes, showing significantly lesser duration of episodes of bloating in HIAW group. The average VAS score for severity of episodes was observed as 21.84 ± 19.40 in HIAW group which was seen as 34.38 ± 14.95 in PDW group, showing significantly lesser intensity/severity of bloating in HIAW group.

Table 8: Assessment of Bloating on VAS score at the end of the study

Parameter	VAS Score (Mean $\pm$ SD)	Avg. Duration in min (Mean $\pm$ SD)	Avg. No of Episodes (Mean $\pm$ SD)
HIAW Group (n = 52)	21.84 $\pm$ 19.40	15.90 $\pm$ 12.18	0.77 $\pm$ 0.76
PDW group (n = 54)	34.38 $\pm$ 14.95	28.50 $\pm$ 18.06	1.39 $\pm$ 1.04
p value (Between)	p = 0.0020 (S)	p = 0.0008 (S)	p = 0.0037 (S)

2) Feeling of acid reflux: In HIAW group there were an average of 0.91 ± 0.66 episodes of feeling of acid reflux while the same was observed to be 1.26 ± 0.58 in PDW group, showing a significantly lesser no of episodes of bloating in HIAW group as compared to PDW group. Similarly, the average duration of these episodes was 16.54 ± 12.04 minutes in HIAW group while in PDW group it was observed to be 29.53 ± 28.54 minutes, showing significantly lesser duration of episodes of feeling of acid reflux in HIAW group. The average VAS score for severity of episodes was observed as 25.77 ± 18.16 in HIAW group which was seen as 42.75 ± 19.21 in PDW group, showing significantly lesser intensity/severity of feeling of acid reflux in HIAW group.

Table 9: Assessment of feeling of acid reflux at the end of the study

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	25.77 $\pm$ 18.16	16.54 $\pm$ 12.04	0.91 $\pm$ 0.66
PDW group (n = 54)	42.75 $\pm$ 19.21	29.53 $\pm$ 28.54	1.26 $\pm$ 0.58
p value (Between)	p = *0.0020 (S) Day 30	p = *0.0008 (S) Day 30	p = *0.0037 (S) Day 30

3) Early fullness during a meal: In HIAW group there were an average of 0.97 ± 0.73 episodes of early fullness during a meal while the same was observed to be 1.37 ± 0.86 in PDW group, showing a significantly lesser no of episodes of early fullness during a meal in HIAW group as compared to PDW group. Similarly, the average duration of these episodes was 13.97 ± 9.67 minutes in HIAW group while in PDW group it was observed to be 26.35 ± 11.71 minutes, showing significantly lesser duration of episodes of early fullness during a meal in HIAW group. The average VAS score of episodes was observed as 25.54 ± 20.21 in HIAW group

which was seen as 33.94 ± 17.62 in HIAW group, showing significantly lesser intensity/severity of early fullness during a meal in HIAW group.

Table 10: Assessment of Early fullness during a meal

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group(n=52)	25.54 ± 20.21	13.97 ± 9.67	0.97 ± 0.73
PDW group (n = 54)	33.94 ± 17.62	21.55 ± 13.95	1.37 ± 0.86
p value (Between)	p = *0.00003 (S) Day 30	p = *0.0041 (S) Day 30	p = *0.0056 (S) Day 30

4) Pain or discomfort in the upper abdomen: In HIAW group there were an average of 1.05 ± 0.79 episodes of pain/discomfort in upper abdomen while the same was observed to be 1.42 ± 0.85 in PDW group, showing a significantly lesser no of episodes of pain/discomfort in upper abdomen in HIAW group as compared to PDW group. Similarly, the average duration of these episodes was 12.62 ± 11.55 minutes in HIAW group while in PDW group it was observed to be 19.72 ± 13.31 minutes, showing significantly lesser duration of episodes of pain/discomfort in upper abdomen in HIAW group. The average VAS score of episodes was observed as 22.61 ± 16.82 in HIAW group which was seen as 33.16 ± 20.01 in HIAW group, showing significantly lesser intensity/severity of pain/discomfort in upper abdomen in HIAW group.

Table 11: Assessment of pain/discomfort in upper abdomen

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	22.61 ± 16.82	12.62 ± 11.55	1.05 ± 0.79
PDW group (n = 54)	33.16 ± 20.01	19.72 ± 13.31	1.42 ± 0.85
p value (Between)	p = *0.0098 (S) Day 30	p = *0.0099 (S) Day 30	p = *0.0099 (S) Day 30

5) Burning in the upper abdomen: In HIAW group there were an average of 0.88 ± 0.85 episodes of burning in upper abdomen while the same was observed to be 1.28 ± 0.75 in PDW group, showing a significantly lesser no of episodes of pain/discomfort in upper abdomen in HIAW group as compared to PDW group. Similarly, the average duration of these episodes

was 21.06 ± 11.71 minutes in HIAW group while in PDW group it was observed to be 26.71 ± 13.06 minutes, showing significantly lesser duration of episodes of pain/discomfort in upper abdomen in HIAW group. The average VAS score of episodes was observed as 17.27 ± 16.74 in HIAW group which was seen as 35.07 ± 17.15 in HIAW group, showing significantly lesser intensity/severity of pain/discomfort in upper abdomen in HIAW group.

Table 12: Assessment of burning in upper abdomen

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	17.27 ± 16.74	10.13 ± 8.55	0.88 ± 0.85
PDW group (n = 54)	35.07 ± 17.15	24.21 ± 18.07	1.28 ± 0.75
p value (Between)	p = *0.00002 (S) Day 30	p = *0.00006 (S) Day 30	p = *0.0220 (S) Day 30

6) Pain/burning sensation in the centre of chest: In HIAW group there were an average of 0.83 ± 0.60 episodes of pain/burning sensation in centre of chest while the same was observed to be 1.26 ± 0.97 in PDW group, showing a significantly lesser no of episodes of pain/burning sensation in centre of chest in HIAW group as compared to PDW group. Similarly, the average duration of these episodes was 15.50 ± 14.14 minutes in HIAW group while in PDW group it was observed to be 32.22 ± 13.72 minutes, showing significantly lesser duration of episodes of pain/burning sensation in centre of chest in HIAW group. The average VAS score of episodes was observed as 23.44 ± 20.20 in HIAW group which was seen as 38.66 ± 18.62 in HIAW group, showing significantly lesser intensity/severity of pain/burning sensation in centre of chest in HIAW group.

Table 13: Assessment of Pain/burning sensation in the centre of chest

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	23.44 20.20	15.50 14.14	0.83 0.60
PDW group (n = 54)	38.66 18.62	24.67 17.83	1.26 0.97
p value (Between)	p = *0.00002 (S) Day 30	p = *0.0046 (S) Day 30	p = *0.0046 (S) Day 30

7) Nausea: In HIAW group there were an average of 0.68 ± 0.52 episodes of nausea while the same was observed to be 1.21 ± 0.74 in PDW group, showing a significantly lesser no of episodes of nausea in HIAW group as compared to PDW group. Similarly the average duration

of these episodes was 8.95 ± 10.13 minutes in HIAW group while in PDW group it was observed to be 19.56 ± 17.71 minutes, showing significantly lesser duration of episodes of nausea in HIAW group. The average VAS score for severity of episodes was observed as 22.04 ± 21.66 in HIAW group which was seen as 32.02 ± 15.36 in HIAW group, showing significantly lesser intensity/severity of nausea in HIAW group.

Table 14: Assessment of Nausea

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	22.04 ± 21.66	8.95 ± 10.13	0.68 ± 0.52
PDW group (n = 54)	32.02 ± 15.36	19.56 ± 17.71	1.21 ± 0.74
p value (Between)	p = **0.1211 (NS) Day 30	p = **0.0415 (NS) Day 30	p = *0.0030 (S) Day 30

8) Vomiting: Non significant difference was observed between the two groups on the symptom, vomiting, at the end of the study in terms of average number of episodes, duration and severity.

Table 15: Assessment of Vomiting

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	19.75 ± 19.52	7.45 ± 9.75	0.59 ± 0.50
PDW group (n = 54)	25.80 ± 19.48	10.00 ± 8.42	0.78 ± 0.46
p value (Between)	p = **0.1860 (NS) Day 30	p = **0.2098 (NS) Day 30	p = **0.1330 (NS) Day 30

9) Burping: In HIAW group there were an average of 0.78 ± 0.63 episodes of burping while the same was observed to be 1.50 ± 0.96 in PDW group, showing a significantly lesser no of episodes of burping in HIAW group as compared to PDW group. Similarly, the average duration of these episodes was 8.79 ± 9.44 minutes in HIAW group while in PDW group it was observed to be 16.95 ± 13.84 minutes, showing significantly lesser duration of burping in HIAW group. The average VAS score of episodes was observed as 18.64 ± 17.67 in HIAW group which was seen as 29.64 ± 16.69 in HIAW group, showing significantly lesser intensity/severity of burping in HIAW group.

Table 16: Assessment of Burping

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	18.64 ± 17.67	8.79 ± 9.44	0.78 ± 0.63
PDW group (n = 54)	29.64 ± 16.69	16.95 ± 13.84	1.50 ± 0.96
p value (Between)	p = *0.0046 (S) Day 30	p = *0.0027 (S) Day 30	p = *0.0002 (S) Day 30

10) Flatulence: In HIAW group there were an average of 0.90 ± 0.55 episodes of flatulence while the same was observed to be 1.24 ± 0.77 in PDW group, showing a significantly lesser no of episodes of flatulence in HIAW group as compared to PDW group. Similarly the average duration of these episodes was 14.25 ± 15.31 minutes in HIAW group while in PDW group it was observed to be 20.15 ± 11.32 minutes, showing significantly lesser duration of flatulence in HIAW group. The average VAS score of episodes was observed as 19.59 ± 14.30 in HIAW group which was seen as 23.77 ± 13.89 in PDW group, showing significantly lesser intensity/severity of flatulence in HIAW group.

Table 17: Assessment of Flatulence

Parameter	VAS SCORE (Mean $\pm$ STDEV)	Avg. Duration (Mean $\pm$ STDEV)	Avg. No of Episodes (Mean $\pm$ STDEV)
Day	Day 30	Day 30	Day 30
HIAW group (n = 52)	19.59 ± 14.30	14.25 ± 15.31	0.90 ± 0.55
PDW group (n = 54)	23.77 ± 13.89	20.15 ± 11.32	1.24 ± 0.77
p value (Between)	p = *0.0013 (S) Day 30	p = *0.0350 (S) Day 30	p = *0.0167 (S) Day 30

B) Assessment of Indigestion and Appetite:

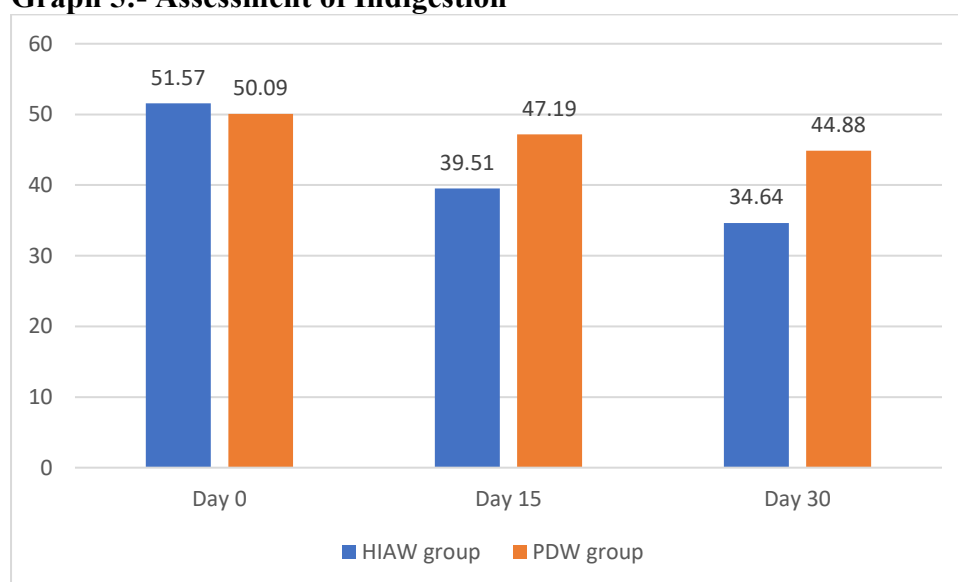
1) Indigestion: The table below shows effect of consumption of water (HAIW and PDW) on indigestion through VAS. The baseline score for indigestion was 51.57 ± 13.80 which reduced significantly to 39.51 ± 21.77 at the end of 15 days and further to 34.64 ± 22.90 at the end of 30 days in HIAW group. In PDW group the score from baseline of 34.64 ± 22.90 reduced non

significantly to 47.19 ± 18.26 at the end of 15 days and significantly to 44.88 ± 19.01 at the end of 30 days. Analysis between the groups showed that HIAW group showed significantly better reduction in indigestion as compared to PDW group at both day 15 and day 30.

Table 18: Assessment of Indigestion

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean $\pm$ SD	51.57 $\pm$ 13.80	39.51 $\pm$ 21.77	34.64 $\pm$ 22.90	50.09 $\pm$ 15.16	47.19 $\pm$ 18.26	44.88 $\pm$ 19.01
p value (Within)	-	0.001 (S)	0.001 (S)	-	0.163 (NS)	0.019 (S)
p value (Between)	p =0.301 (NS) Day 0, p =0.024 (S) Day 15 & p =0.006 (S) Day 30					

Graph 5:- Assessment of Indigestion



2) Appetite:

The table below shows effect of consumption of water (HAIW and PDW) on appetite through VAS. There was a non-significant difference from baseline to 15 days and further 30 days in both the groups. Analysis between the groups also showed non-significant difference between the two groups.

Table 19: Assessment of Appetite

Group	HIAW group (n = 52)			PDW group (n = 54)		
Day	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Mean $\pm$ STDEV	60.20 $\pm$ 15.30	59.53 $\pm$ 17.95	59.42 $\pm$ 21.12	57.12 $\pm$ 15.79	58.55 $\pm$ 16.47	56.21 $\pm$ 16.81
p value (Within)	-	**0.339 (NS)	**0.742 (NS)	-	**0.408 (NS)	**0.650 (NS)
p value (Between)	p = **0.158 (NS) Day 0, p = **0.378 (NS) Day 15 & p = **0.198 (NS) Day 30					

C) Global Assessment for Overall Change by Investigator and Participant:

Assessment of overall change as per the investigator and the participants showed that as per the investigator a total of 12(23.08%) participants reported of very much improvement, 27(51.92%) of much improvement and 13(25.00%) of minimal improvement in HIAW group. None of the participants in this group showed no change or worsening in their condition. In PDW group 2(3.70%) participants reported of much improvement, 28(51.85%) of minimal improvement and 24(44.44%) participants showed no change as per the investigator.

Similarly, as per the participants 17(32.69%) participants in A group showed very much improvement, 21(40.38%) showed much improvement and 13(25.00%) showed minimal improvement while 1(1.92%) participant showed no change on the overall effect. In PDW group, 2(3.70%) participants reported of very much improvement, 1(1.85%) of much improvement and 28(51.85%) of minimal improvement. 23 (42.59%) participants showed no change while none of the participants reported of worsening in their condition.

Table 20: Assessment of Global Assessment for Overall Change by Investigator and Participant

Observation	Overall change by investigator		Overall change by participants	
	HIAW group (n = 52)	PDW group (n = 54)	HIAW group (n = 52)	PDW group (n = 54)
0 = Not assessed	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 = Very much improved	12 (23.08%)	0 (0%)	17 (32.69%)	2 (3.70%)
2 = Much improved	27 (51.92%)	2 (3.70%)	21 (40.38%)	1 (1.85%)
3 = Minimally improved	13 (25.00%)	28 (51.85%)	13 (25.00%)	28 (51.85%)
4 = No change	0 (0%)	24 (44.44%)	1 (1.92%)	23 (42.59%)
5 = Minimally worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 = Much worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)
7 = Very much worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Safety Assessment:

A. Global Assessment of Overall Safety by Investigator and Participant:

Global assessment of overall safety as per the investigator, showed that of the 52 participants in HIAW group 23 (44.23%) were reported of excellent overall safety 17 (32.69%) of good overall safety and 12 (21.15%) of fair overall safety. None of the participant reported on poor

overall safety. In PDW group, of the 54 participants, 13 (24.07%) were reported of excellent overall safety, 22 (40.74%) of good overall safety and 19 (12.96%) of fair overall safety.

Global assessment of overall safety as per the participant, showed that of the 52 participants in HIAW group 23 (44.23%) were reported of excellent overall safety 17 (32.69%) of good overall safety and 12 (21.15%) of fair overall safety. None of the participant reported on poor overall safety. In PDW group, of the 54 participants, 13 (24.07%) were reported of excellent overall safety, 20 (37.04%) of good overall safety and 21 (20.37%) of fair overall safety.

Table 21: Assessment of Safety

Observation	Overall change by investigator		Overall change by participants	
	HIAW group (n = 52)	PDW group (n = 54)	HIAW group (n = 52)	PDW group (n = 54)
0 = Excellent Overall safety	23 (44.23%)	13 (24.07%)	23 (44.23%)	13 (24.07%)
1 = Good Overall safety	17 (32.69%)	22 (40.74%)	17 (32.69%)	20 (37.04%)
2 = Fair Overall safety	12 (21.15%)	19 (12.96%)	12 (21.15%)	21 (20.37%)
3 = Poor Overall safety	0	0	0	0

B. Assessment of Vital Signs

The below table shows effect of consumption of HIAW and PDW on vital parameters over a period of 30 days. There were non-significant changes from baseline to follow up visits. The values were within normal range for all the parameters for all study visits.

Table 22: Assessment of Vital Signs

Day/Parameter	HIAW group (n = 52)			PDW group (n = 54)		
	Day 0	Day 15	Day 30	Day 0	Day 15	Day 30
Pulse (/min)	80.98 ±4.95	79.81 ±4.68	80.10 ±5.60	79.91 ±7.62	80.43 ±6.35	79.85 ±6.85
Respiration (/min)	18.67 ±2.46	19.23 ± 2.16	18.98 ±1.95	18.56 ±2.58	18.98 ±1.90	19.09 ±2.24
Temperature (degree C)	97.26 ±1.34	97.29 ±1.20	97.38 ±1.11	97.16 ±1.20	97.26 ±1.26	97.26 ±1.23
BP (Sys) (mm of Hg)	118.29 ±9.07	118.88 ±7.87	118.15 ±7.28	118.24 ±8.23	119.30 ±7.61	118.93 ±7.85
BP (Dia) (mm of Hg)	77.54 ±5.95	76.50 ±5.91	76.23 ±5.10	76.06 ±6.57	76.81 ±5.39	76.56 ±5.86
p value (Between)	p>0.05 (NS) for all parameters					

C. Assessment of Adverse Events:

There was a total of 5 AE in HIAW group and 9 AE in PDW group. Details of AE are provided in the table below. None of the AE were observed to be related to the consumption of water ion both the study groups.

CONCLUSION

The study concludes that consumption of HAIW showed a significant reduction in symptoms of hyperacidity like acid reflux, pain in abdomen, bloating, burning sensation in the chest and flatulence. These effects were observed within 15 days of starting consuming HAIW and continued further till 30 days. The reduction in these symptoms were found to be significantly better as compared to packaged drinking water. Based on the results of this study, HAIW can be safely consumed without causing any adverse effects and improves important physiological functions including management of hyperacidity. These findings support the potential of Hydron Alkaline Ionized Water as a safe, health-promoting functional beverage for healthy adults with hyperacidity.

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Conflict of Interest

The study was sponsored by Hydron Alkaline Aqua Pvt. Ltd., Mumbai, which provided the investigational product, Hydron Alkaline Ionized Water (HAIW), and funded the conduct of the clinical study. The sponsor was involved in the study design and provision of the study product but had no role in data collection, statistical analysis, interpretation of results, or the decision to submit the manuscript for publication. The authors declare that the findings reported in this manuscript are based solely on the clinical data collected during the study and have been reported objectively and without bias. All authors have reviewed and approved the final manuscript and declare no other competing interests.

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LIST OF ABBREVIATIONS

Abbreviation	Full Form
AE/AEs	Adverse Event(s)
CRF/CRFs	Case Report Form(s)
CTRI	Clinical Trial Registry of India
GCP	Good Clinical Practice
GERD	Gastro Esophagus Reflux Disease
GSRS	Gastrointestinal Symptom Rating Scale
HAIW	Hydron Alkaline Ionized Water
HCL	Hydrochloric Acid
ICF	Informed Consent Form
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IP	Investigational Product
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OPD	Out Patient Department
ORP	Oxidation Reduction Potential
PDW	Packaged Drinking Water
PIS	Participant Information Sheet
PUD	Peptic Ulcer Disease
SAE/SAEs	Serious Adverse Event(s)
TDS	Total Dissolved Solids
VAS	Visual Analogue Scale
BMI	Body Mass Index