ISSN 0973-2063 (online) 0973-8894 (print)

Bioinformation 22(8): 4698-4704 (2026)

BIOINFORMATION
Discovery at the interface of physical and biological sciences

BIOMEDICAL INFORMATICS

www.bioinformation.net

Volume 22(8)

Research Article

Received August 1, 2026; Revised August 31, 2026; Accepted August 31, 2026, Published August 31, 2026

DOI: 10.6026/973206300224698

SJIF 2026 (Scientific Journal Impact Factor for 2026) = 8.478
2022 Impact Factor (2023 Clarivate Inc. release) is 1.9

Edited by P Kangueane

Citation: Mishra *et al.* Bioinformation 22(8): 4698-4704 (2026)

Immediate intragastric acid neutralization with botanical granules

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ISSN 0973-2063 (online) 0973-8894 (print)
Bioinformation 22(8): 4698-4704 (2026)

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Abstract:
Gastroesophageal Reflux Disease (GERD) results from backflow of acidic gastric secretions (pH 1–2) into the oesophagus, for which Dabur India Ltd. developed antacid powder DRDC/2022/040 containing *Nimbu Satva* (*Citrus medica*), *Peppermint Satva* (*Mentha piperita*) and *Sarjikshara* (sodium bicarbonate) for acid neutralization. A crossover clinical study (n=32) evaluated intragastric pH via nasogastric probe over 15-minute baseline and 60 minutes post-consumption, with 36–48 hour washout. Group-1 (n=15, DRDC/Water sequence) showed significant pH increase from baseline 1.97 ± 0.55 to 2.56 ± 1.02 at 2 seconds post-DRDC ($p<0.05$), with no change following water crossover. While Group-2 (n=16, Water/DRDC sequence) showed significant pH increase upon DRDC crossover (baseline 1.67 ± 0.42 to 4.07 ± 1.02 at 10 seconds, $p<0.05$), versus no change with water. Thus, DRDC/2022/040 exhibits potent antacid activity with onset within 2–3 seconds, effectively neutralizing intragastric acidity.

Keywords: Gastroesophageal Reflux Disease (GERD) symptoms, intragastric pH, antacid, peppermint satva, *Citrus medica*, sodium bicarbonate

Background:
Food undergoes into three types of processes in the body namely digestion, absorption and elimination/excretion **[1]**. The digestion involves conversion of complex food molecules into simple absorbable form through mechanical, chemical and enzymatic action **[2]**. The gastric acid *i.e.* HCl produced by parietal cells of lumen is tightly regulated through neural and hormonal mechanisms involving several epithelial cell types **[3]**. Approximately 3 L of gastric juice per day secreted by the human gastric glands, which possess ~0.17 N HCl content with pH around 1.5 – 3.5 **[4]**. This physiological sphincter (~ 3 to 5 cm long) prevents regurgitation of gastric contents into the esophagus **[5]**. The Gastroesophageal reflux disease (GERD), is a condition in which the stomach contents leak backward from the stomach into the oesophagus, due to improper closure of sphincter of muscle **[6]**. A range of conditions such as eating large or heavy meals or lying down right after a meal, obesity, intake of spicy foods, consuming baked items *etc.* could lead to GERD **[7]**. In the recent past, a vast change was noticed in lifestyle such as less physical activity, sedentary workstyle, sleep pattern (less than 6 – 8 h), work place pressures *etc*. aggravating the GERD prevalence **[8]**. The prevalence of GERD in India ranges from 7.6% to 30%, being < 10% in most population studies and higher in cohort studies **[9]**. GERD symptoms include heartburn, regurgitation and chest pain. Heartburn characterised by burning sensation primarily felt behind the sternum within 60 minutes of eating. The pain commonly starts in the epigastrium and radiates towards the neck. Sour or burning fluid in the throat or mouth typically characterizes acid regurgitation **[6]**. Treatment for GERD categorised into patients with minimal to moderate symptoms were advised for lifestyle modifications and PPI therapy with additional pharmacologic treatment when indicated. Whereas, patients suffering with severe symptoms of GERD, as well as non-respondents were advised for long-term treatment or invasive procedures such as laparoscopic fundoplication or magnetic sphincter augmentation **[10]**. Apart from allopathic treatment, the natural botanical-based formulations were also reported in traditional system of medicine **[8]**. Herbal antacids comprised of exclusively botanicals or combination of botanicals and salts such as bicarbonates, aluminum hydroxides act as digestion promoters, acid-neutralizers, inhibitors of gastric acid secretion **[11]**. Combination treatment strategy was proposed for development of dual action formulations which act through immediate symptomatic relief via alkaline buffering activity (especially such as carbonates) and plant bioactives exerts their action through muco-protective, anti-inflammatory and cytoprotective properties **[12]**. In view of the stated background Dabur India Ltd., has developed a formulation with combination of salts and botanicals. Dabur's antacid powder (DRDC/2022/040), each 5 g comprised of powders of Peppermint (*Pudina*) Satva (Menthol) derived from *Mentha species*, *Nimbu Satva/ Nimbukamlam* (Dried fruit juice of *Citrus medica)* and *Sarjikshara* (Sodium Bicarbonate) along with artificial sweeteners, permitted excipients and colors. Therefore, it is of interest to report the current study on DRDC/2022/040, which was evaluated for its efficacy in terms of gastric acid pH neutralization in relation with time in healthy volunteers against the water as placebo.

Methodology:
Test formulation (DRDC/2022/040) was supplied by Dabur India Ltd., Ghaziabad. Each 5g of DRDC/2022/040 contains powders of *Peppermint* (*Pudina*) *Satva* - 0.0015g (Menthol) derived from *Mentha species*, *Nimbu Satva/ Nimbukamlam* (Dried fruit juice of *Citrus medica*) - 2.243g and *Sarjikshara* (Sodium Bicarbonate) - 2.638g along with artificial sweeteners (Sucralose -

0.0176g), permitted excipients and colours. A total of 32 participants, aged 18 – 55 years were recruited with due approvals from Institutional Ethics Committee of Dr. Mhaske Hospital & Research Center Pvt. Ltd., Pune, India and subsequent registration with CTRI (CTRI/2023/08/056221). The schematic flow of the study was given in **Figure 1** and entire concept explained diagrammatically in **Figure 4**.

The inclusion criteria followed was:

[1] Healthy male & females,
[2] Clinically normal physical findings,
[3] Laboratory values (CBC, CT, BT, Liver profile) within the normal range,
[4] Female participants with negative urine pregnancy test
[5] Ready to sign informed consent form and follow study procedure.

The exclusion criteria adopted was:

[1] Immuno-compromised participants or suffering from any serious or debilitating medical condition,
[2] Drug, tobacco or alcohol abuse,
[3] Diabetes/hypertension,
[4] Any disease/condition or physical defect which impacts study procedures,
[5] Who are on medication which could have altered or influenced stomach acidity or study drug/placebo activity,
[6] Participants who were unsuitable to participate in the study per investigator,
[7] Participant who had participated in any other clinical trial in the previous 30 days and
[8] Pregnant and Lactating females.

Upon recruitment into the study written consent was obtained by explaining the study procedures and making understanding the participants in regional language. The information such as age, height and weight was recorded along with blood pressure (systolic and diastolic). Blood was collected from all the participants and analysed haematological parameters viz. fasting blood sugar, Hb%, ESR, platelets, clotting & bleeding time and liver function tests. The study participants were divided into two groups viz. Group-1: DRDC/water (n=16) and Group-2: Water/DRDC (n=16). Prior to one hour of dosing, nasogastric probe (ZepHr ComforTEC Z/pH Probe part no-ZANBG 44) was positioned in the antral region of the stomach of overnight fasting participants, using standard technique. Participant allowed for stabilization (20 – 45 min), followed by baseline gastric pH data was recorded (15 min). Then participants were asked to consume ether DRDC/2022/040 as per manufacturer instructions or water as quickly as possible in 30 sec. Intragastric pH was monitored and recorded continuously for 60 minutes. Post this, the probe was taken out, participants were observed for 30 min, examined, if any, untoward event during study procedures and were relieved for the day. This procedure was repeated to all the participants after 36 – 48 h of wash period, when they were cross overed to respective test compound or water.

The outcome measures include:

[1] Effect of DRDC/2022/040 on gastric acid neutralization compared to placebo (water) through pH monitoring over 60-min;
[2] Time needed for 'one pH unit change' compared water;
[3] Time needed to achieve a pH of 3.5 or greater compared to water.

In addition, the safety evaluation through assessment of AE, SAEs and concomitant medications during the study.

Statistical analysis:

The data was compiled and computed for statistical analysis. All the quantitative parameters were expressed as mean ± Standard Deviation (SD). Qualitative variables were presented as counts and percentage. Comparison of variables representing categorical data was performed using chi-square or Fisher's exact test. Comparative assessment within the group and between the groups was done by paired sample t test and un-paired t test respectively. All p-values were reported based on two-sided significance test and all the statistical tests were interpreted at 5% level of significance level.

Table 1: Anthropometry profile of participants

S. No.	Parameter	DRDC/Water (n=16)	Water/DRDC (n=16)
1	Age (Years)	34.94 ±9.86	29.44 ±10.09
2	Body Weight (Kg)	67.81 ±10.18	63.75 ±7.33
3	BMI (Kg/m²)	25.51 ±3.72	23.87 ±2.39

Values are mean±SD.

Table 2: Haematological profile of participants

S. No.	Parameter		DRDC/Water (n=16)	Water/DRDC (n=16)
1	Blood Pressure (mm of Hg)	Systolic	118.13 ±4.03	116.75 ±4.49
		Diastolic	78.75 ±3.86	80.38 ±4.57
2	Fasting Sugar (mg/dL)		83.88 ±13.29	84.32 ±9.75
3	Hb (g%)		13.94 ±1.53	14.39 ±1.97
4	Bleeding Time (min)		12.87 ±1.81	12.91 ±1.30
5	Clotting Time (min)		27.56 ±3.68	28.61 ±2.95
6	Platelets (Lakhs/µL)		2.61 ±0.66	2.63 ±0.52
7	ESR (mm/hour)		8.44 ±6.55	7.81 ±6.81
8	Liver Function Tests	Total Bilirubin (mg/dL)	0.81 ±0.39	0.92 ±0.48
		AST (U/L)	28.50 ±5.70	30.31 ±5.84
		ALT (U/L)	28.63 ±10.83	25.75 ±9.02

Values are mean±SD. ESR: Erythrocyte Sedimentation Rate; AST: Aspartate aminotransferase; ALT: Alanine aminotransferase.

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Table 3: Time vs 'pH change' from baseline

S. No.	Parameter		Group 1 (n=16)		Group 2 (n=16)		Combined (n=32)	
			DRDC	Water	Water	DRDC	DRDC	Water
1	Time taken to achieve '1 unit pH Change (Sec)		4.00 ±2.63	57.18 ±91.08	122.44 ±223.59	3.56±1.36	3.78 ±2.07	79.80 ±204.19
2	No. of participants achieving 1 unit pH change over	In '1 min.'	16 (100%)*	6 (37.5%)	5 (31.25%)*	16 (100%)	32 (100%)*	11 (34.4%)
3		In '60 min.'	16 (100%)*	10 (62.5%)	10 (62.5%)*	16 (100%)	32 (100%)*	20 (62.5%)
4	Time taken to achieve 'pH 3.5' (Sec)		4.12 ±2.06	338.2 ±669.28	1004.2±1308.47	4.93±2.11	4.53 ±2.09	671.20±1265.07

*Values are mean±SD; *significantly different with respective cross over test compound/water within group.*

Table 4: Vitals – pulse, body temperature, blood pressure

S. No.	Parameter	Group 1				Group 2			
		DRDC/2022/040		Water		Water		DRDC/2022/040	
		Before	After	Before	After	Before	After	Before	After
1	Pulse (Per min)	80.50 ±5.49	80.25 ±5.05	80.31 ±5.25	80.38 ±3.03	79.94 ±3.37	80.63 ±2.80	80.56 ±5.69	80.38 ±3.59
2	RR (Per min)	20.88 ±2.80	20.69 ±1.40	21.75 ±3.19	20.69 ±1.20	22.00 ±2.83	21.00 ±2.80	22.00 ±2.50	20.25 ±1.61
3	Temp (^{0}C)	97.66 ±2.80	97.13 ±0.64	97.46 ±1.10	97.50 ±0.72	97.48 ±0.58	97.19 ±0.62	97.60 ±0.68	97.76 ±0.68
4	BP (Sys) (mm of Hg)	118.13 ±4.03	124.13 ±7.50	118.88 ±3.50	118.63 ±9.14	120.13 ±0.50	120.63 ±8.85	119.10 ±4.54	118.63 ±7.99
5	BP (Dia) (mm of Hg)	78.75 ±3.86	78.88 ±6.41	78.50 ±3.46	74.00 ±4.44	80.38 ±4.57	77.88 ±7.78	79.13 ±4.19	73.50 ±3.54

Values are mean±SD; RR: Respiration Rate; BP: Blood Pressure

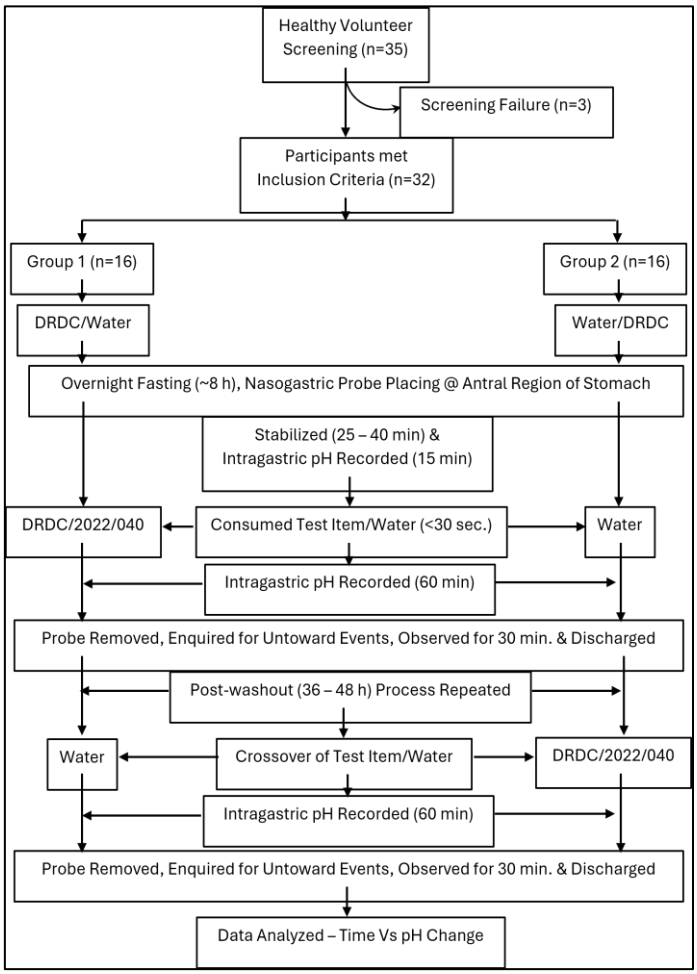

Figure 1: Schematic flow of study and process – from patient selection as per the inclusion criteria to final data analysis

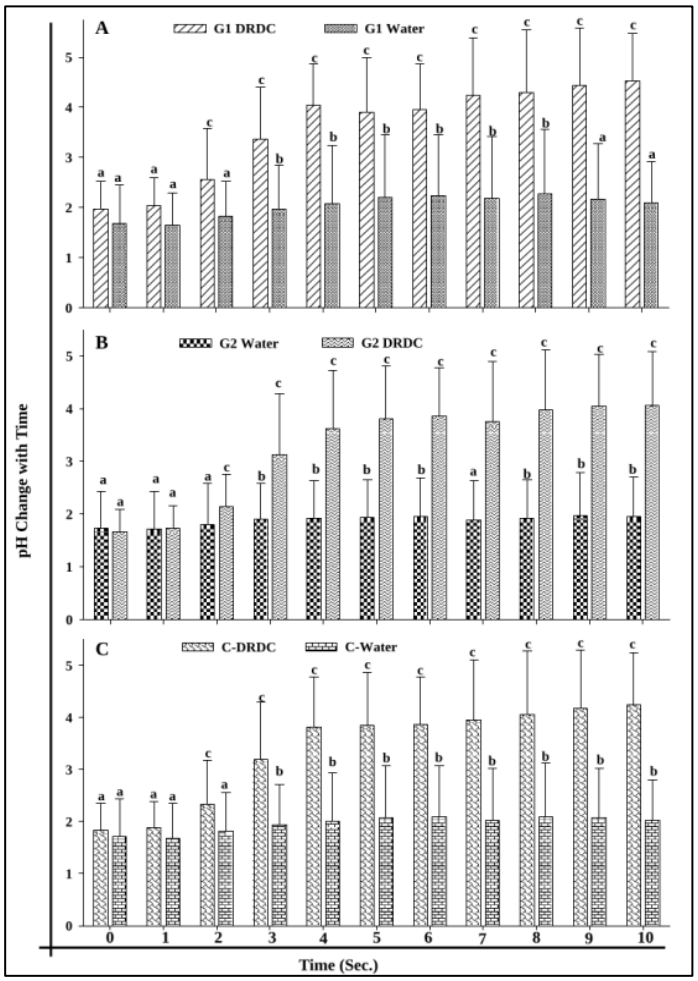

Figure 2: Intragastric pH change: The intragastric pH was recorded for 1 hour. Bars represent mean±SD of intragastric pH

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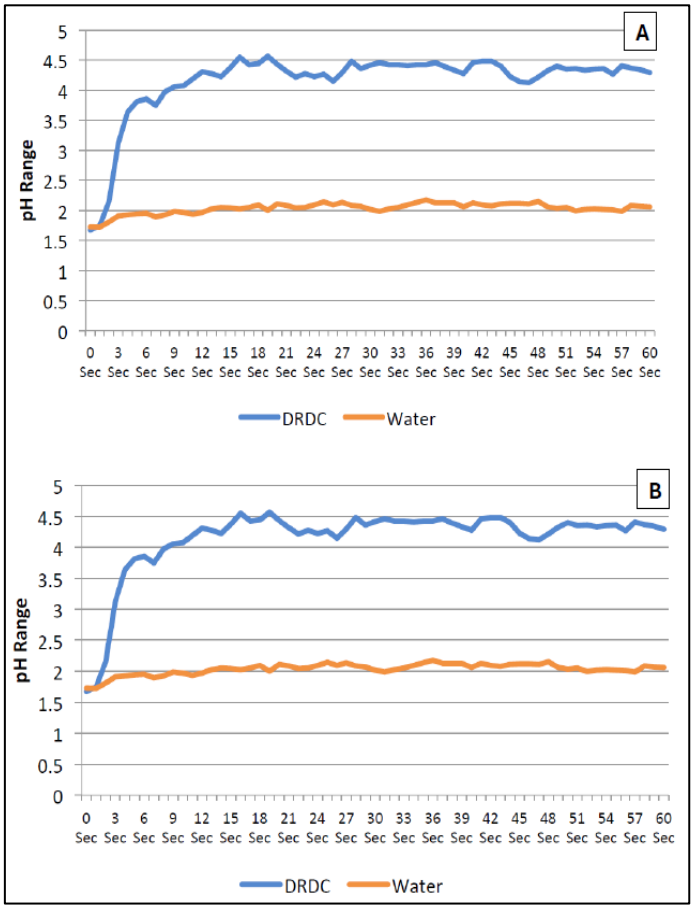

Figure 3: pH Change over 60 min upon consumption of DRDC/2022/040 or Water. The line graph represents mean intragastric pH information of the participants. A. Group 1 participants, intragastric pH data when consumed the DRDC/2022/040 and cross overed to water post-wash period (36-48h). B. Group 2 Participants, intragastric pH data when consumed water and cross overed to DRDC/2022/040 post-wash period (36-48h)

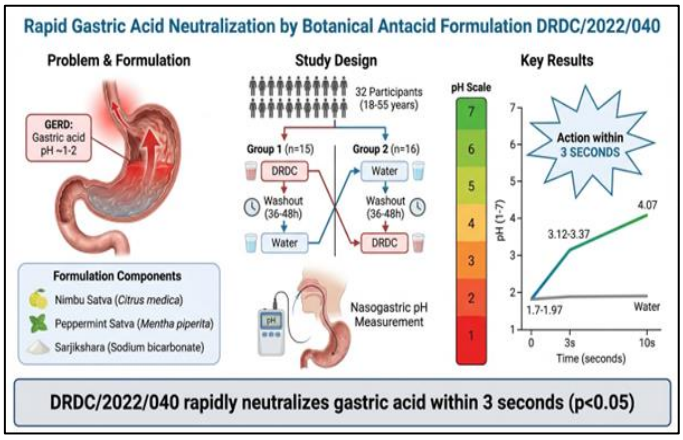

Figure 4: Schematic representation of the research approach from problem to key results

Results and Discussion:

The anthropometric profile viz. age, weight and BMI of the participants were given in **Table 1**. The mean age of participants was comparable between groups. DRDC/Water group participants age was ranged from 22 – 51 years, while Water/DRDC group participants age ranged from 20 – 54 years. In DRDC/water group there were 8 males and 8 female participants. Whereas in Water/DRDC group 12 male and 4 female participants. The body weight and BMI were comparable between groups (**Table 1**). The haematological profile includes haemoglobin, erythrocyte sedimentation rate (ESR), platelets, bleeding and clotting time along with liver function tests (Total bilirubin, ALT & AST) of the participants were given in **Table 2**. Fasting blood sugar levels were within normal range and were comparable between the groups. The blood pressure (Systolic and Diastolic), ESR, bleeding & clotting time suggests the participants of DRDC/Water and Water/DRDC were healthy **(Table 2)**. In addition, the liver function tests viz. total bilirubin, Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) were with normal range and comparable between two groups. The baseline information of intragastric pH among DRDC/water group ranges from 1.3 - 4.4 with mean value of 2.17 ±0.76 and when the same participants cross overed to water treatment the baseline pH was ranged from 0.6 – 4.9 with mean of 1.85 ±1.10. Similarly, the data of Water/DRDC participants baseline pH ranges from 1.21 – 3.50 with mean of 1.86 ±0.67, whereas when cross overed to DRDC the mean baseline pH was 1.69 ±0.63, ranging from 1.1 – 3.8 **(Figure 4)**. The mean gastric acid pH levels at 0^{th} second in Group 1 (n=15) was 1.97±0.55; upon consumption of DRDC/2022/040 the increase in intragastric pH was noted from 2^{nd} Sec. onwards. The significant ($p<0.05$) increase was noted from 3^{rd} sec 3.37±1.03 compared to 0^{th} Sec. The similar effect was noted in progress with time and at 10^{th} Sec. the mean intragastric pH was 4.52 ±0.96, which was significantly ($p<0.05$) higher than 0^{th} sec (**Figure 2A**). Whereas, the same participants when cross overed to Water as treatment, the mean intragastric pH levels at 0 second was 1.68 ±0.77 and not increased even after 10^{th} Sec. (2.10 ±0.82), as shown in (**Figure 2A)**. Among the participants (n=16) of Group 2, who consumed water had the mean gastric acid pH levels of 1.73±0.71 at 0^{th} Sec. and remains almost same at 10^{th} Sec. (1.96 ±0.75) (**Figure 2B**). This data suggesting no change in intragastric acid pH levels when consumed water. Nevertheless, the same participants when cross overed and consumed the DRDC/2022/040 have shown significant increase in intragastric pH levels from 3^{rd} Sec. (3.12 ±1.16) onwards compared to 0^{th} Sec. (1.67 ±0.42). This effect was continued up to 10^{th} Sec. (4.07±1.02) and significant compared to 0^{th} Sec (**Figure 2B**). The data of intragastric acid pH levels of participants who consumed DRDC/2022/040 from Group 1 (n=15) and Group 2 (n=16) was combinedly analysed. The mean intragastric pH levels were 1.84 ±0.51 at 0^{th} Sec., upon consumption of DRDC/2022/040 the change in pH was noted from 2^{nd} Sec. (2.33 ±0.84) and continued to 10^{th} Sec (4.25 ±1.00). At 3^{rd} sec. the mean pH levels were 3.19 ±1.10 which was significantly ($p<0.05$) compared to 0^{th} Sec. Whereas the mean intragastric pH levels almost unchanged over

period of initial 10 seconds who consumed the water (**Figure 2C**). The mean pH change over 60 min of Group 1 and 2 participants when consumed either DRDC/2022/040 or water was given in (**Figure 3)**. The information about the 'pH Change' in relation with time was given in **Table 3**. Time taken to achieve '1 unit change of pH' by the participants consumed DRDC/2022/040 was significantly ($p<0.05$) less in Group 1 (4.00 ± 2.63 sec.), Group 2 (3.56±1.36 sec.) and combined (3.78 ±2.07 sec.) in comparison to respective water consumption participants (**Table 3**). Similarly, the average time taken to achieve intragastric 'pH 3.5 and above' was ~4 sec., by the participants upon consumption of DRDC/2022/040. Within 'one minute' all the participants who consumed DRDC/2022/040 has achieved the pH change of one unit, whereas only 6 participants from Group 1 and 5 participants from Group 2 have achieved when consumed water (**Table 3**). A total of 6 adverse events (AEs) like itching in the nose (n=4), one nausea and one episode of vomiting was noted during the study period among the participants. Whereas all these AEs were related to 'nasogastric tube' placement procedure, but not related to test compound exposure. There were no SAEs reported in the study. The pulse, temperature, blood pressure and respiration rate showed no significant change from baseline to the end of the study and were observed to be within normal limits (**Table 4**). Although causes of GERD are unknown, several risk factors such as obesity, the consumption of heavy meal, spicy and fatty foods and the use of non-steroidal anti-inflammatory drugs (NSAIDs)/aspirin *etc.* are associated with GERD **[8]**. Lack of physical activity, lying down right after a meal were also considered as risk factor of GERD **[13]**. The studies conducted by Wang *et al.* have reported that the dietary fiber and regular physical activity provide protection from GERD **[14]**. Treatment options for GERD include antacids (neutralize gastric acid), drugs act through inhibition of gastric acid production: Histamine-2-receptor antagonists (H2RA), PPIs and potassium-competitive acid blockers (P-CAB) **[6]**. Use of antacids is symptom-based treatment of dyspepsia or reflux, including heartburn. Antacid in the current study is comprised of *Peppermint (Pudina) Satva* (Menthol), *Nimbu Satva/ Nimbukamlam* (Dried fruit juice of *Citrus medica)* and *Sarjikshara* (Sodium Bicarbonate). Intragastric acid pH levels were significantly ($p<0.05$) increased from 3 sec. of post-consumption of DRDC/2022/040 compared to water (**Figure 2**). Menthol's protective action was reported through mucus secretion elevation and PGE2 production, stimulating K^+ATP channels, decreasing the H^+ concentration in gastric juice and exerting antioxidant and anti-inflammatory effects **[15, 16]**. Other ingredient the *Nimbu Satva / Nimbukamlam* (Dried fruit juice of *Citrus medica)* was proven for its antioxidant activity of eriocitrin, hesperidin, sakuranetin and rutin, these major phenolic compounds of citron showed anti-inflammatory, anti-diabetic and anticancer activities **[17]**. The gastro-oesophageal protective effect of formulations consists of sodium bicarbonate, which either neutralise gastric acid and act as antacids or induce the formation of a protective film on the gastric mucosa (sodium alginate and carbonate/bicarbonate) **[12]**. In addition, all the participants, who consumed DRDC/2022/040 have shown 'one unit of gastric acid pH increase' at a mean time of 3.78 ±2.07 sec. compared to water. Suggesting it's early action in neutralization of intragastric pH. On the other hand, 34% of the participants achieved this 'one unit pH change' in '1 minute', when consumed 'water' (**Table 3**). The antacid property of current formulation was attributed to the ingredients viz. menthol and sodium bicarbonate, known to exert their action by decreasing proton concentration and neutralization property respectively **[12, 15 and 16]**. The vitals viz., blood pressure, pulse, body temperature, respiration rate were comparable before and after treatment with test compound (DRDC/2022/040). Further, the test compound associated AEs / SAEs were not reported by the participants during the study period. This information suggests the safety profile of the test compound.

Conclusion:

We show that DRDC/2022/040 has quick gastric acid neutralizing ability, which action starts from 3rd sec. of consumption as compared to water. This property would be useful in management of symptoms of GERD like heart burn, acidity and indigestion.

Advancement to Knowledge:

This quantified onset-of-action data for a botanical salt combination formulation is a meaningful contribution to the GERD management literature, as it bridges traditional medicine with evidence-based pharmacological evaluation, showing that a non-prescription, plant derived antacid can deliver rapid symptomatic relief comparable in speed to conventional antacids while maintaining a favourable safety profile with no treatment-related adverse events. These findings support the clinical utility of dual-action formulations that combine alkaline buffering (sodium bicarbonate) with mucosa-protective botanical bio-actives (menthol, citrus phenolics), offering a scientifically validated, accessible alternative for mild-to-moderate GERD symptom management.

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