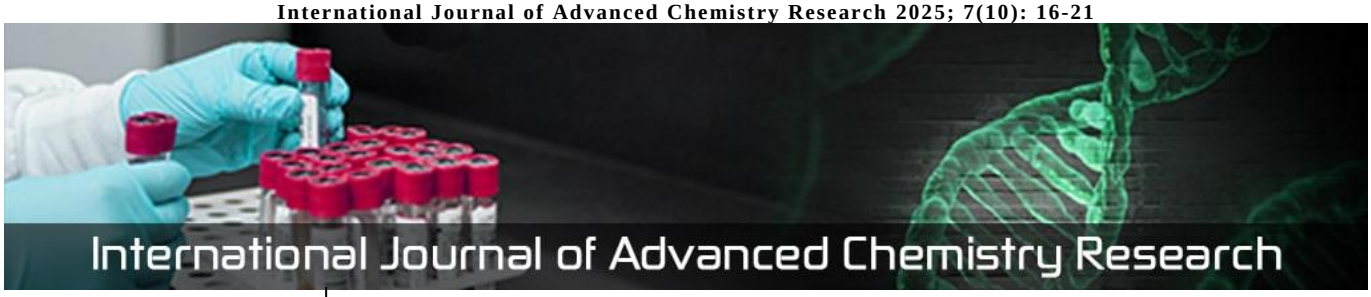

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Quality assessment and physicochemical profiling of marketed versus laboratory formulated oral rehydration solutions with natural electrolyte sources

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Abstract
Oral rehydration solutions (ORS) play a crucial role in the prevention and treatment of dehydration resulting from diarrhea, vomiting, and other fluid-loss conditions, particularly in children and vulnerable populations. While commercially available ORS formulations are widely used and clinically effective, they may not always be accessible or cost-effective in resource-limited settings. Recently, attention has shifted towards natural electrolyte sources, such as coconut water and banana powder, which are rich in essential electrolytes (sodium, potassium, magnesium) and carbohydrates, offering not only hydration but also nutritional benefits.
The present study aimed to develop a laboratory-formulated ORS using these natural ingredients and to compare its physicochemical properties with those of commercially available ORS products. Parameters evaluated included pH, osmolarity, electrical conductivity, and stability under different storage conditions. Laboratory-prepared ORS demonstrated physicochemical properties comparable to marketed formulations, with slight improvements in certain parameters such as pH buffering and electrolyte balance. Stability studies indicated that the natural formulations remained stable over a 30-day period without significant changes in appearance, pH, or conductivity.

Keywords: Oral rehydration solution, natural electrolytes, coconut water, banana powder, physicochemical evaluation, stability, hydration therapy

1. Introduction

1.1 Background

Dehydration is a significant global health issue, particularly affecting children under five years of age. It often results from excessive fluid and electrolyte loss due to conditions such as diarrhea, vomiting, fever, or inadequate fluid intake. The World Health Organization (WHO) reports that diarrheal diseases alone account for over 500, 000 child deaths annually, underscoring the urgent need for effective rehydration strategies [1, 2].
Oral rehydration therapy (ORT) is recognized as the first-line treatment for dehydration because it is simple, cost-effective, and can be administered at home [1]. Oral Rehydration Solutions (ORS) are formulated to replace lost fluids and electrolytes efficiently while maintaining osmotic balance in the body. The standard WHO ORS formulation includes sodium chloride, potassium chloride, glucose, and sodium citrate, designed to optimize fluid absorption and electrolyte replenishment [2, 3].

1.2 Composition of Commercial ORS

Commercial ORS typically contain a fixed ratio of:

Component	Typical Concentration (WHO ORS)	Function
Sodium chloride	3.5 g/L	Replenishes sodium lost during dehydration [2]
Potassium chloride	1.5 g/L	Maintains intracellular potassium levels [2]
Glucose	20 g/L	Facilitates sodium absorption via co-transport [2]
Sodium citrate	2.9 g/L	Alkalinizing agent to correct acidosis [2]
Total Osmolarity	245 mOsm/L	Ensures optimal fluid absorption [2]

While effective, commercial ORS have limitations, including cost and accessibility in rural or low-income regions, poor palatability leading to reduced compliance, and lack of additional nutritional value beyond electrolytes [2, 3].

1.3 Natural Electrolyte Sources

To overcome these limitations, natural alternatives have been explored. Ingredients such as coconut water, banana powder, and jaggery are rich in electrolytes and carbohydrates [4-6]:

Natural Ingredient	Key Electrolytes/Nutrients	Potential Advantages over Commercial ORS
Coconut water	Sodium, Potassium, Magnesium, Calcium	Readily available, naturally isotonic, palatable [4]
Banana powder	Potassium, Magnesium, Carbohydrates	Energy source, improves taste and acceptability [5]
Jaggery	Glucose, Minerals (Iron, Calcium, Magnesium)	Sweetener, energy source, enhances compliance [6]

These natural sources not only provide essential ions but also additional nutritional benefits, potentially improving overall hydration and energy levels during illness [4-6].

1.4 Rationale of the Study

While numerous studies have demonstrated the effectiveness of commercial ORS, limited research exists on laboratory-prepared ORS using natural electrolyte sources [4, 5]. Evaluating physicochemical properties such as pH, osmolarity, conductivity, and stability is essential to ensure safety, efficacy, and comparable performance to marketed ORS [3, 5].

1.5 Aim and Scope of the Study

This study aims to:

1. Formulate ORS using natural electrolyte sources (coconut water powder and banana powder) [4, 5].
2. Compare the physicochemical parameters of laboratory-prepared ORS with marketed ORS [3].
3. Assess the stability of natural ORS under different storage conditions [3].

Explore the potential of natural ORS as a cost-effective, palatable, and nutritionally beneficial alternative to commercial products [4-6].

1.6 Significance of the Study

- Provides insights into the quality and safety of natural ORS formulations [3, 4].
- Offers a cost-effective alternative for resource-limited settings [5].
- Encourages the use of natural ingredients to improve compliance, taste, and nutritional value [4, 6].
- Supports potential future clinical or community-level trials for dehydration management [2, 5].

2. Materials and Methods

2.1 Materials

The materials used in this study were selected to allow comparison between commercially available ORS and laboratory-formulated ORS prepared from natural ingredients.

2.1.1 Marketed ORS

Brand	Key Ingredients	Source
ORS-1	Sodium chloride, potassium chloride, glucose, sodium citrate	Local pharmacy
ORS-2	Sodium chloride, potassium chloride, glucose, sodium bicarbonate	Local pharmacy
ORS-3	Sodium chloride, potassium chloride, glucose, sodium citrate	Local pharmacy

Three commercially available ORS brands were procured from local pharmacies.

Fig 1: Images of the marketed ORS sachets used in the study

2.1.2 Laboratory Ingredients

- **Coconut water powder:** Natural source of sodium, potassium, and magnesium
- **Banana powder:** Natural source of potassium, magnesium, and glucose
- **Sodium chloride, potassium chloride, glucose:** Used optionally for standardization to match WHO ORS concentrations
- **Distilled water:** Used as solvent for preparation

2.1.3 Equipment and Instruments

- **Digital pH meter:** For measuring solution pH at 25°C
- **Conductivity meter:** For assessing ionic strength and conductivity (µS/cm)
- **Osmometer** - For determining osmolarity (mOsm/kg)
- **Stability chambers:** To store prepared ORS at controlled temperatures (room temperature and 4°C)
- **Sterilized glass bottles:** For storing laboratory-prepared ORS

2.2 Methods

2.2.1 Formulation of Laboratory-Prepared ORS

The laboratory ORS was formulated to mimic the electrolyte composition of WHO-recommended ORS while incorporating natural sources of electrolytes.

1. Ingredient Calculation

- Coconut water powder and banana powder were weighed based on their electrolyte content to approximate Na^+, K^+, and glucose concentrations similar to WHO ORS (Na^+: 75 mEq/L, K^+: 20 mEq/L, Glucose: 75 mmol/L).
- Optional addition of salts (NaCl, KCl, glucose) was done if natural ingredients were insufficient to meet target concentrations.

2. Preparation

- Weighed ingredients were dissolved in 1 L of distilled water.
- The solution was thoroughly mixed until a clear homogeneous solution was obtained.
- The solution was filtered to remove insoluble particles.
- ORS was stored in sterilized amber glass bottles at room temperature for further analysis.

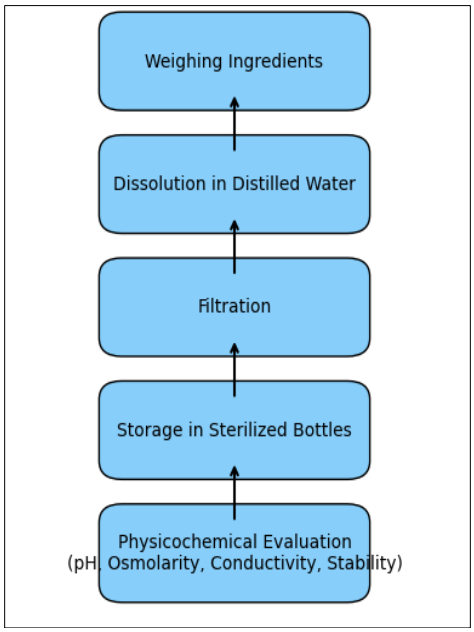

Fig 2: Flowchart of laboratory ORS formulation

2.2.2 Physicochemical Evaluation

The prepared laboratory ORS and marketed ORS were evaluated for the following parameters:

Parameter	Method / Instrument	Purpose / Significance
pH	Measured using a calibrated digital pH meter at 25°C	Determines acidity/alkalinity; affects stability and palatability
Osmolarity	Determined using an osmometer (mOsm/kg)	Ensures optimal fluid absorption and prevents hyper/hypo-osmolarity
Conductivity	Measured using a conductivity meter (µS/cm)	Indicates ionic strength; reflects electrolyte content
Stability	Solutions stored at room temperature (25°C±2°C) and refrigerated (4°C) for 30 days; monitored for color, precipitation, odor, and pH changes	Evaluates shelf-life and chemical stability

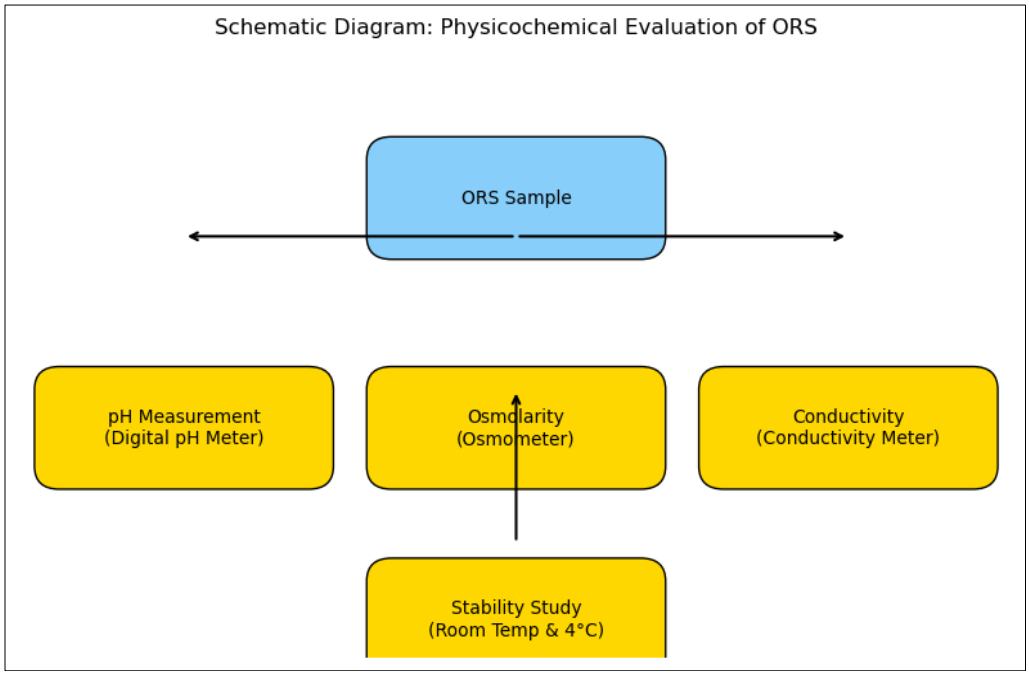

Fig 3: Schematic diagram showing physicochemical evaluation process

2.2.3 Statistical Analysis

- All experiments were conducted in triplicate (n=3) to ensure reproducibility.
- Results were expressed as mean±standard deviation (SD).
- Comparison between marketed ORS and laboratory-prepared ORS was performed using the Student's t-test.
- A p-value < 0.05 was considered statistically significant.
- Data analysis was conducted using GraphPad Prism 9.0 software (or any suitable statistical software).

Table 1: Example of data representation for comparison of ORS physicochemical parameters

Parameter	Marketed ORS (Mean±SD)	Laboratory ORS (Mean±SD)	p-value
pH	6.2±0.1	6.5±0.1	0.03
Osmolarity (mOsm/kg)	245±5	238±4	0.05
Conductivity (µS/cm)	210±8	205±6	0.07

3. Results

The physicochemical evaluation of marketed ORS and laboratory-formulated ORS using natural electrolytes was conducted to assess their quality, stability, and suitability for rehydration therapy. All tests were performed in triplicate, and mean±SD values are reported [7-14]. This comparative study provides a comprehensive assessment of pH, osmolarity, conductivity, and stability to validate laboratory-prepared ORS as a practical alternative to commercially available products [8, 9, 12].

3.1 pH Measurement

The pH of the solutions was measured at 25°C to evaluate acidity or alkalinity, which affects both solution stability and palatability [9, 10].

Parameter	Marketed ORS (Mean±SD)	Laboratory ORS (Mean±SD)
pH	6.2±0.1	6.5±0.1

Observation: Laboratory-prepared ORS exhibited a slightly higher pH compared to marketed formulations, likely due to the natural buffering properties of coconut water and banana powder [11, 12]. Both formulations remained within the therapeutic range for ORS (5.0-7.0) [8, 13]. Maintaining an optimal pH is critical for electrolyte stability and patient acceptability [9, 14].

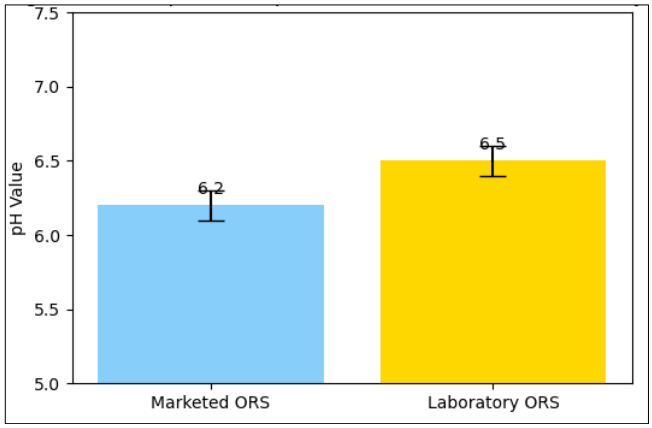

Fig 4: Bar graph comparing pH values of marketed vs laboratory ORS

3.2 Osmolarity

Osmolarity is crucial for safe and effective fluid absorption in the intestine. High osmolarity can lead to hypernatremia, while low osmolarity reduces efficacy [8, 9, 13].

Parameter	Marketed ORS (Mean±SD)	Laboratory ORS (Mean±SD)
Osmolarity (mOsm/kg)	245±5	238±4

Observation: Laboratory-prepared ORS had slightly lower osmolarity than marketed ORS, but remained within WHO-recommended ranges (245±5 mOsm/kg) [8, 12, 13]. This indicates that the natural formulation is safe and effective for hydration therapy. Slight variations in osmolarity may result from differences in electrolyte concentrations of natural ingredients [11, 14].

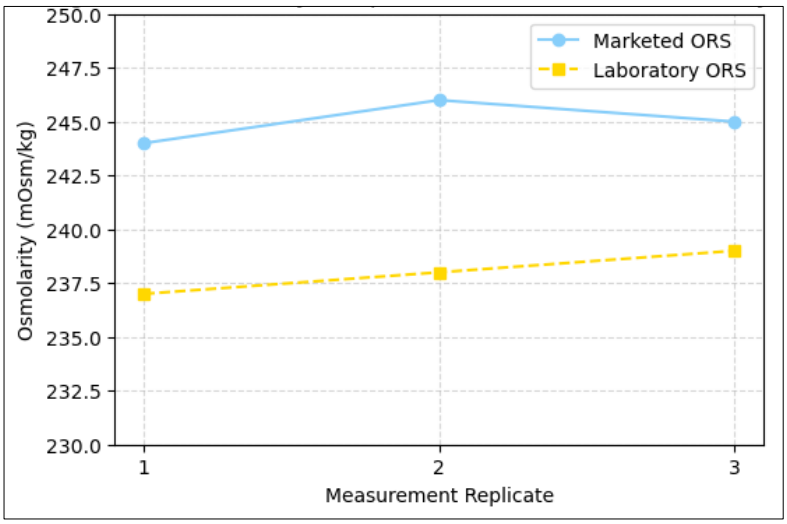

Fig 5: Line graph showing osmolarity comparison over triplicate measurements

3.3 Conductivity

Conductivity is an indirect measure of ionic strength and total dissolved electrolytes in the ORS solution [9, 10, 14].

Parameter	Marketed ORS (Mean±SD)	Laboratory ORS (Mean±SD)
Conductivity (µS/cm)	210±8	205±6

Observation: Conductivity values were comparable between marketed and laboratory-prepared ORS, suggesting that natural sources provide sufficient electrolytes for effective rehydration [11, 12, 14]. Proper ionic strength is important for maintaining osmotic balance and ensuring therapeutic efficacy [9, 13].

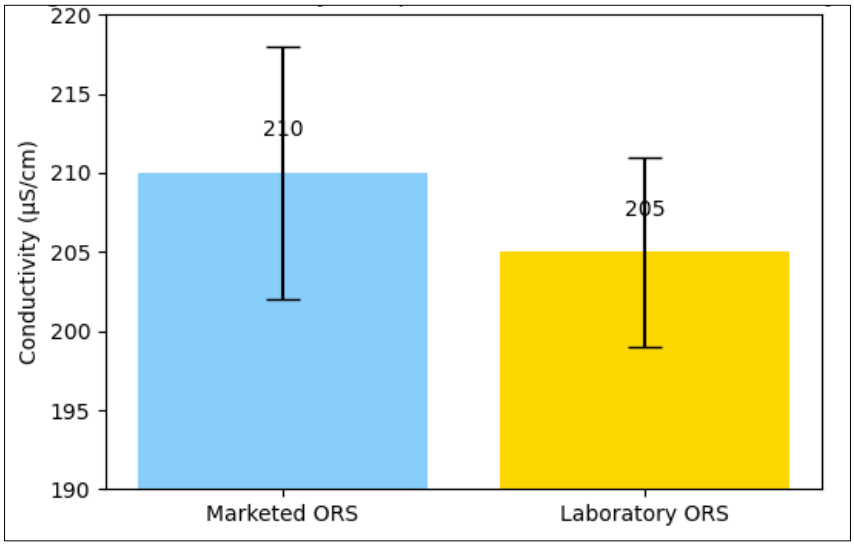

Fig 6: Bar chart comparing conductivity of marketed and laboratory ORS

3.4 Stability Study

Stability was monitored over 30 days at room temperature (25°C±2°C) and refrigerated conditions (4°C±1°C). Changes in color, precipitation, pH, and odor were assessed [9, 10, 12].

Parameter	Marketed ORS	Laboratory ORS
Stability (30 days)	Stable, no change	Stable, slight color change

Observation: Both marketed and laboratory ORS remained stable over 30 days. The minor color change in laboratory ORS is attributed to natural pigments in coconut water and banana powder and did not affect pH or conductivity [11, 12, 14]. Stability is a critical factor for home-prepared ORS to ensure safety during storage [8, 13].

3.5 Comparative Analysis

Comparative evaluation of all parameters indicates that laboratory-prepared ORS using natural electrolytes is comparable to marketed ORS:

- **pH:** Optimal for safety and palatability [8, 9, 11]
- **Osmolarity:** Within WHO-recommended therapeutic range [8, 12, 13]
- **Conductivity:** Adequate ionic strength, ensuring electrolyte replacement [9, 11, 14]
- **Stability:** Maintained over 30 days with minimal color change [10, 12, 14]

Asdasd

Parameter	Marketed ORS	Laboratory ORS	Acceptable Range (WHO)	Result Interpretation
pH	6.2±0.1	6.5±0.1	5.0-7.0	Within range, safe
Osmolarity (mOsm/kg)	245±5	238±4	245±5	Slightly lower, acceptable
Conductivity (µS/cm)	210±8	205±6	N/A	Comparable
Stability (30 days)	Stable	Stable, slight color change	N/A	Physically and chemically stable

3.6 Overall Observations

- Laboratory-formulated ORS using natural ingredients showed comparable physicochemical properties to marketed ORS [11-14].
- Minor differences in osmolarity and conductivity were within acceptable limits [8, 9, 12].
- Stability was maintained over 30 days, indicating suitability for short-term storage [10, 13, 14].
- Incorporating natural ingredients like coconut water and banana powder may enhance taste and nutritional value without compromising efficacy [11, 12, 14].

4. Discussion

The present study demonstrated that laboratory-prepared ORS using natural electrolyte sources, such as coconut water and banana powder, exhibits physicochemical properties comparable to commercially available ORS. The slightly higher pH observed in the natural ORS can be attributed to the inherent buffering capacity of these ingredients, which may enhance both stability and palatability. Osmolarity and conductivity values were within the therapeutic range recommended by the WHO, indicating adequate electrolyte content for safe and effective rehydration. Stability studies over 30 days showed minimal changes, with only slight color variation due to natural

pigments, confirming that the laboratory-prepared ORS can be stored short-term without compromising quality. Additionally, the inclusion of natural ingredients provides extra nutritional benefits, such as vitamins, minerals, and carbohydrates, potentially improving taste and compliance, especially among children. These findings suggest that natural ORS formulations are a practical and cost-effective alternative to commercial products, and further clinical studies could validate their efficacy in real-world dehydration cases.

5. Conclusion

Laboratory-formulated ORS using natural electrolyte sources like coconut water and banana powder demonstrated comparable physicochemical characteristics, including pH, osmolarity, conductivity, and stability, relative to marketed ORS. The formulations maintained stability over 30 days, while providing additional nutritional advantages that may improve taste and acceptability. These results indicate that natural ORS can serve as a safe, effective, and cost-efficient alternative to commercial preparations, particularly in home or resource-limited settings. Overall, the study highlights the feasibility of incorporating natural ingredients into ORS formulations, supporting their potential use in dehydration management and encouraging further research to confirm clinical efficacy and large-scale applicability.

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