Research Article

Development And Clinical Evaluation Of A Wearable Bio-Electromagnetic Quantum Therapeutic System From Elaeocarpus Ganitrus For Cardiovascular Supportive Therapy

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Abstract

Background
Cardiovascular diseases remain one of the leading causes of global morbidity and mortality, necessitating the development of novel complementary therapeutic approaches. Elaeocarpus ganitrus possesses unique mineralized crystalline architecture enriched with quartz, silicate, calcium, and ferrous constituents that may exhibit bio-electromagnetic properties. The present study aimed to investigate the physicochemical characteristics, bio-electromagnetic potential, safety profile, and preliminary cardiovascular supportive efficacy of a novel Cryptokinetic Transient Energy (CKTE)-based therapeutic system developed from pulverized Elaeocarpus ganitrus seed.

Methodology
Authenticated E. ganitrus seeds were pulverized and characterized using scanning electron microscopy (SEM), Fourier-transform infrared spectroscopy (FTIR), ferro/piezoelectric analysis, membrane permeability testing, and electromagnetic field (EMF) interference studies. The powdered formulation was incorporated into wearable patches and sachets intended for external precordial application. A pilot clinical investigation involving twelve cardiovascular patients receiving standard pharmacotherapy was subsequently conducted following institutional ethical approval. Clinical outcomes were evaluated using electrocardiography (ECG), echocardiography (ECHO), blood pressure (BP), pulse rate (PR), and retrieval rate toward normal physiological status (Rr).

Results and Discussion
SEM analysis demonstrated crystalline clusters composed predominantly of calcium-aluminium silicate embedded within a ferrous oxide matrix. FTIR analysis confirmed the presence of silicate, alumina, hydroxyl, and aliphatic functional groups. Ferroelectric evaluation revealed significant polarization stability ($F=4.666$, $P=0.0312$), indicating sustained piezoelectric behavior. EMF analysis demonstrated appreciable dielectric absorptive wave interference, whereas membrane permeability studies confirmed complete absence of transmembrane penetration, suggesting external non-invasive activity. Preliminary clinical findings indicated favorable improvements in ECG, ECHO, BP, PR, and physiological recovery indices following adjunctive CKTE administration, without evidence of local irritation or adverse reactions.

Conclusion
The findings suggest that the CKTE-based wearable therapeutic system derived from Elaeocarpus ganitrus exhibits promising bio-electromagnetic, piezoelectric, and cardiovascular supportive properties with an excellent safety profile. However, larger randomized controlled studies are warranted to validate its therapeutic efficacy and elucidate the underlying mechanisms of action.

Keywords: Elaeocarpus ganitrus; Cryptokinetic Transient Energy; Bio-electromagnetic Quantum therapy; Cardiovascular disease; Wearable therapeutic system; Electromagnetic modulation.

1. Introduction

The phrase “cardiovascular disease,” or simply “CVD,” refers to a wide range of disorders affecting the cardiovascular system, blood vessels, and coronary arteries, making it one of the leading global health challenges [1]. Conditions categorized under CVD include cardiac arrest, stroke, hypertension or high blood pressure, and coronary artery disease (CAD), each of which can result in serious or fatal consequences [2]. Cardiovascular disease, which includes strokes, is the most prevalent cause of death and illness globally. For instance, in this nation alone, over 50 million people suffer from hypertension, and 62 million experience some form of cardiovascular disease [3].

Epidemiological research and randomized clinical investigations have demonstrated a strong relationship between coronary artery disease and modifiable risk factors such as dyslipidemia, hypertension, and lifestyle factors [4]. Cardiovascular disease (CVD) remains a leading cause of death worldwide. Despite advances in medical interventions that have improved survival rates and quality of life for individuals with CVD, its prevalence continues to rise, and necessitating new and innovative treatment approaches [5-6]. Dysregulation of lipid metabolism plays a significant role in the pathogenesis of CVD [7]. Standard clinical lipidology focuses on lipid classifications such as total triglycerides and low-density lipoprotein cholesterol, but emerging lipidomic technologies provide deeper insights into the pathogenesis of diseases such as atherosclerosis, coronary artery disease, and heart failure [8-11].

Atherosclerosis, defined as the build-up of fats, cholesterol, and other substances in and on artery walls, is the primary cause of most cardiovascular events, further emphasizing the need for innovative therapeutic approaches [12-13].

Elaeocarpus has 300 species, 35 of which have been identified in India. The primary species of this genus is Elaeocarpus ganitrus, commonly known as the "rudraksha tree." It is found from the Gangetic region in the foothills of the Himalayas to Nepal, South and Southeast Asia, as well as Australia, Guam, and Hawaii. Rudraksha fruits contain alkaloids, flavonoids, tannins, steroids, triterpenes, carbohydrates, and cardiac glycosides, including Rudrakine, an alkaloid first identified in 1979 [14-15].

3D wave harmonizing quantum wave field regulating concept referring to transient energy generated through molecular magnetism within crystalline structures exhibiting piezoelectric properties. Specifically, this kind of positive focuses on the energy generated as macroscopically content in seeds of Elaeocarpus ganitrus (Rudraksha), which contain trace amounts of crystalline silica (quartz). When mechanical stress (e.g., shear movement or pressure due to squeeze drying or wet bulge) is applied to these crystals, they produce an electric biocompatible charge via the well-established piezoelectric effect. The generation of bioelectrical charges in crystalline structures has been extensively studied. For example, bone exhibits piezoelectric properties, and the electrical potentials generated by mechanical stress are believed to contribute to bone remodeling and growth. Although these signals are weak, they may interact with the body's endogenous electrical systems, potentially modulating nerve impulses or influencing other bioelectrical processes. Electromagnetic fields (EMFs) are known to interact with biological systems, affecting cellular communication, membrane dynamics, and even gene expression. Studies have shown that EMFs can influence cell surface chemical events, including the binding of hormones, antibodies, and neurotransmitters, by amplifying the initial weak triggers at their receptor sites (Liboff, 1993). This phenomenon suggests that EMFs can modulate cellular signal transduction, potentially altering physiological processes. Further research has demonstrated that extremely low-frequency electromagnetic fields (ELF-EMFs) can impact neuronal function, affecting synaptic activity, neurotransmitter release, and overall neural communication (Wang et al., 2023). These effects are of particular relevance to cardiovascular health, where neural regulation plays a critical role in maintaining heart rate and vascular tone [16-17].

Similarly, the mechanical-electrical transduction mediated by mechanosensitive ion channels (PIEZO1 and PIEZO2) is crucial for various physiological functions, including touch perception and vascular development [18].

The interaction between bioelectromagnetism and living tissues is not limited to animal systems. In plants, certain species have been shown to generate and utilize bioelectromagnetic fields for cellular communication and environmental response (Cifra, Fields & Farhadi, 2011). This aligns with the concept of same, which proposes that Elaeocarpus ganitrus seeds, due to their crystalline silica content, can generate bioelectromagnetic energy through piezoelectric effects. The quartz crystals within these seeds can produce electric charges when subjected to mechanical stress, potentially influencing cellular functions through electromagnetic interactions. By integrating these scientific principles, 3D wave harmonizing quantum wave field conceptualized as a form of bio-electromagnetic energy derived from natural crystalline structures, with potential applications in cardiovascular stabilization. We hope this enhanced introduction provides a clearer and scientifically robust understanding of the theoretical foundation of 3D wave harmonizing quantum wave field regulating concept [19].

Apart from that the type of quantum wave energy persisting material also acquires three dimensional wave-kinetic harmonizing energy like higher efficiency than a conventional treatment of neuro-psychological disorders. One such theory is that quantum wave energy with a desired oscillation, stored in particular crystalline or metallic complex structures, may have an impact on biological systems. Electrical signaling is a fundamental aspect of both animal and plant physiology. In plants, electrical signals such as action potentials and variation potentials are involved in processes including growth, defense, and response to environmental stimuli. For example, the Venus flytrap (Dionaea muscipula) utilizes electrical signals to trigger rapid leaf closure upon mechanical stimulation, an example of how bioelectrical energy can lead to physiological responses [20]. This three-dimensional wave harmonizing energy is also we can name as Crypto-Kinetic Transient Energy (CKTE). In order to produce a mechanical oscillation within a precisely sized slab of monocrystalline silica—which can be found naturally as quartz or, more commonly, artificially synthesized from an aqueous solution at extremely high pressure and temperature—quartz crystal and its potassium and ferrous silicate complex, which are found the seed of Elaeocarpus Ganitrus. The cause of the quartz crystal resonator's monotonic frequency characteristics is its extraordinarily high effective Q value (a quartz crystal oscillator's "Q" value, also known as its quality factor, is a measure of its efficiency and stability) [21]. α-Quartz is the stable phase of silica SiO_2 at ambient conditions. In this arrangement, the Si and O atoms create a tridimensional network of SiO_4 tetrahedra by sharing four corners. Because of the strong covalent character of the Si–O–Si bonds, α-quartz does not have a plane with weak bonds into which dislocations may easily slide. The shortest lattice repeats are c = 0001, a = 1 3 〈 11 2 ¯ 0 〉 , and c ± a = 1 3 〈 11 2 ¯ 3. The water-related impurities in quartz seem to have a very significant effect over dislocation mobilities liberate bioelectromagnetic

wave. [22-23]. Bio-electromagnetic wave may influence biomaterial physiology, affecting tissue, cellular, and biomolecular pathways either positively or negatively. This unexplored energy form could offer potential therapeutic applications.
The intersection of geology, metallurgy, and pharmacology has gained interest recently due to the potential applications of CKTEF in medical sciences. The phrase "crypto-kinetic transient energy flux" refers to the fleeting and often cryptic energy patterns exhibited by metallic ores. Medications for cardiac diseases provide therapeutic benefits, such as preventing arterial clots, but their efficacy diminishes in advanced cases. This necessitates additional or complementary therapies that can enhance treatment outcomes and reduce the need for invasive procedures.
Historically significant, rudraksha beads have been used in spiritual practices and are believed to exert calming effects on the nervous system, potentially benefiting cardiovascular health by lowering stress and anxiety. Some practitioners suggest that rudraksha beads have electromagnetic properties that aid in regulating blood pressure and circulation. To analyze the seed sample (Elaeocarpus ganitrus, EG), we conducted several analytical tests, including scanning electron microscopy (SEM) for structural analysis, Fourier-transform infrared spectroscopy (FTIR) for chemical composition, and electromagnetic field (EMF) testing to investigate potential wellness-promoting properties.
SEM provides high-resolution images for examining the microstructure of EG seeds at different scales. FTIR identifies functional groups by analyzing infrared absorption spectra, offering critical insights into the chemical composition and potential therapeutic benefits of the seeds. Piezoelectric technology was also employed to validate the authenticity and purity of the seeds, as authentic samples generate an electric charge in response to mechanical stress. These complementary techniques aim to uncover the medicinal potential of Elaeocarpus ganitrus in addressing cardiovascular disease and other health conditions.
As a new strategy for the treatment of cardiovascular diseases (CVD), cryptokinetic transient energy flux (CKTEF) is proposed in this study. Adverse medication responses and declining effectiveness in advanced instances of cardiovascular disease are two limits of traditional treatment techniques, not withstanding their considerable break through. An uncharted energy form called CKTEF has recently emerged from metallic ores like Elaeocarpus ganitrus; this finding marks a new frontier at the crossroads of quantum physics, metallurgy, and pharmaceuticals. The purpose of this study is to examine the possible therapeutic uses of CKTEF by analysing the unique bio-electromagnetic characteristics of Elaeocarpus ganitrus like seeds. The findings might lead to safer and more effective therapies that supplement or augment traditional treatments. This research contributes uniquely to the field of cardiovascular health by conducting a comprehensive analysis of the medicinal potential of this plant using novel techniques such as piezoelectric technology, scanning electron microscopy (SEM), Fourier-transform infrared spectroscopy (FTIR), and electromagnetic field (EMF) testing.

2. Literature Survey

2.1. Herbal Remedies for Cardiovascular Disease
Ancient herbal remedies are known for their safety and lack of adverse effects, making them crucial in developing treatments for conditions like cerebral and venous insufficiency, angina, atherosclerosis, and heart failure [24]. Chronic stable angina and acute coronary syndromes are often linked to atherosclerosis, with treatment focusing on secondary prevention and symptom relief through antianginal and disease-modifying drugs [25]. However, limitations such as the risk of bleeding, dosing challenges, and inconsistent treatment efficacy in arterial thrombosis underscore the need for alternative solutions, including natural remedies and non-invasive techniques [26].

2.2. Medicinal Properties of Elaeocarpus ganitrus
Elaeocarpus ganitrus (Rudraksha), native to India, has a rich history in traditional medicine for treating neurological, gynecological, and cardiovascular conditions, among others [27]. Its seeds contain bioactive compounds like carbohydrates, tannins, flavonoids, steroids, saponins, and cardiac glycosides. Studies suggest that Rudraksha exhibits antifungal properties, allowing extended storage and potential artificial regeneration to enhance seed availability [28]. The plant is also believed to have unique therapeutic effects on conditions such as diabetes, high blood pressure, and mental anxiety, yet its precise mechanisms remain underexplored**.**

2.3. Electromagnetic Properties of Elaeocarpus ganitrus
Elaeocarpus ganitrus likes seeds having quartz crystal possess significant electromagnetic, conductive, and piezoelectric properties, which may have therapeutic implications. These properties, attributed to their inductive, resistive, dielectric, and magnetic characteristics, suggest potential applications in regulating physiological processes like blood pressure and stress response [29, 30]. The therapeutic behavior of Elaeocarpus ganitrus beads, particularly the five-Mukhi variant, is claimed to benefit individuals with diabetes, tension, and neurotic disorders, although scientific validation remains limited.

2.4. Gaps in Current Research

Despite its historical use and widespread belief in its health benefits, scientific studies evaluating the specific effects of Elaeocarpus ganitrus Mukhi variants on cardiovascular diseases are sparse [25]. Furthermore, while Elaeocarpus ganitrus is known for its electromagnetic properties, the interplay between these properties and its bioactive compounds in therapeutic contexts is poorly understood. This highlights a critical gap in the literature, underscoring the need for multidisciplinary approaches to study these mechanisms.

3. Methodology

3.1. Comparative advantages of 3D quantum wave based bio-electromagnetic field over the existing conventional cardiovascular treatments:

Here basically, the control on heart rate was regulated by the medicine. The tachycardia, fibrillations and cardiac flutters are stepwise pathophysiological consequential results of coronary atherosclerosis, cardiac Ischemia, myocardial Infraction (MI) and finally Cardiac heart failure (CHF), as per the state and degree of complication. Three-dimensional wave harmonizing quantum wave is a CKTE which has optimal liberation of low frequency of α, β, γ, δ compatible with brain waves, which interfere with action potential of cardiac conduction neurons to stabilize and statics to homeostasis of its intensity as well as. Other than that the vascular smooth muscle produce action potentials, the depolarizing current is carried by voltage-dependent L-type Ca^{2+} channels. The resting membrane potential is primarily determined by K^+ permeability due to the abundance of K^+ channels. Small changes in membrane potential can significantly impact calcium entry and contraction, even without a full action potential. Thus, the 3D harmonizing quantum wave control the vascular action potential and calcium influx, which is responsible for atherosclerosis.

3.2. Source, Collection, and Authentication of Elaeocarpus ganitrus Seed

The seeds were collected from the Forest and Environmental Department, Sikkim, during the winter season on 10-01-2024. The crude fruit weight was 100 g, color: dark red, texture: rough, average size: ~7 mm, and the total seed count: 502. The seeds were harvested in the morning from non-defective fruits (no discolored or overripe fruits) on 16-12-2023 and transported to the Sikkim market.

Authentication Process: The seeds were authenticated by a certified taxonomist using morphological and anatomical characteristics, verified against reference herbarium specimens, and documented with authentication certificate no. (File. No. 11 UTI / GOS / F&ED.) Dated: 09/01/2024 from the Forest Research Center.

3.3. Pulverization of seed for Instrumental Analysis

Fifty grams (50g) of dried Elaeocarpus ganitrus seeds were finely pulverized using a high-speed mixer-grinder, and the powder particle size was standardized to 50–100 µm through mesh sieving. The pulverized material was subsequently dehumidified under controlled conditions to attain a moisture content below 5% and evaluated for flow characteristics by determining the angle of repose. The processed powder was then stored in airtight, moisture-resistant containers for further investigations. Quality control and homogeneity of the formulation were validated using Fourier Transform Infrared Spectroscopy (FTIR) and Scanning Electron Microscopy (SEM).

The pulverized powder was prepared for instrumental analysis and formulation into patches and sachets. Figure 1 illustrates the stages: a) Monocotyledon seed Elaeocarpus ganitrus, b) Grinding process, c) Fine powder ready for further testing.

Figure 1: a) Monocotyledon seed Elaeocarpus ganitrus, b) Seed into the grinder, b) Pulverization of Elaeocarpus ganitrus Seed, c) Fine Powder.

3.4. Membrane Permeability Test

To evaluate the transmembrane permeability of the investigational formulation, an in-vitro membrane permeation study was performed using isolated duck egg membrane as a biological barrier model. The membrane was carefully separated and preserved in 5% clove water until use. Subsequently, 0.1 g of the pulverized drug sample was dispersed in an aqueous medium, and the test tube containing the formulation was sealed with the prepared membrane and maintained in an inverted position for 15–20 min. Following exposure, the opposite surface of the membrane was examined by Scanning Electron Microscopy (SEM) to assess the presence of penetrated particles. Additionally, a bio-mimetic permeability assessment was conducted by incorporating the drug material into an Aloe vera gel matrix and applying it onto the membrane in the presence of 95% ethanol and water as permeation media. Parallel control experiments without the drug formulation were performed to establish baseline membrane permeability characteristics.

3.5. EMF Interference Analysis of EG

Electromagnetic field (EMF) characterization was performed using a validated EMF meter to quantify electric field strength (E, V/m) and magnetic field strength (H, µT). The instrument was initially calibrated using blank samples to ensure analytical accuracy. Subsequently, the dielectric absorptive and electromagnetic shielding properties of the drug-incorporated patches were evaluated by measuring their ability to attenuate external EMF interference. Furthermore, the CKTE-associated bio-electromagnetic potential of the formulation was assessed to investigate its putative influence on neurocellular membrane stabilization.

3.6. Fourier-transform infrared spectroscopy (FTIR): FTIR spectrometer is collecting the high-resolution information throughout a broad spectral range (between 4000 and 400 cm^{-1}), a clear benefit over a dispersive spectrometer, which measures power simultaneously over a small range of frequencies. Main Aim of spectroscopy techniques is (FTIR (UV–V) spectroscopy) to measure the amount of light that a sample absorbs at every frequency [31].

3.7. Ferro/Piezo-Electric Evaluation

The piezoelectric properties of the formulation were evaluated using high-stress acoustic and actuation systems (Table S2). The instrumental analysis was performed on Ferroelectric loop tester (PLC21018-405), Model – LC- II precision, version 5.18.1; Manufacturer: - Radiant Instrument inc., USA, which is having processor of x86 (AMD or Intell)-4. The Internal Ampere (Amp) type is 100V Rev F Slow, internal Amp S/N- Iab1-419/F.

1. Permittivity and Dielectric Loss Testing: The dielectric and piezoelectric displacement properties were measured under high driving voltages using an NPL system (Figure S4).
2. Instrumentation: The system utilized an IEEE bus-controlled digital storage oscilloscope (DSO), high-voltage amplifiers, and displacement measurement devices to capture the piezoelectric response. Figure S5 outlines the setup schematic.

The f-ratio value is **0.62402.** The p-value is **0.647533.** The result is not significant at $p < .05$**.**

4. Clinical Investigation

4.1. Formulation and Encapsulation of the Investigational Powder

The investigational powder formulation was encapsulated in customized sachets fabricated from pharmaceutical-grade butter paper. Sachets of predefined dimensions were prepared and sealed using a biocompatible, chemically inert Aloe vera gel-based adhesive to maintain formulation integrity and minimize contamination. Following partial sealing, the powdered formulation was accurately filled into the sachets under aseptic conditions, and the remaining opening was hermetically sealed using the same adhesive system. The sealed sachets were allowed to dry for 10–15 min to ensure complete adhesion and stabilization. Prior to clinical application, all sachets were visually inspected for uniformity, sealing efficiency, leakage, and structural integrity.

4.2. Methodology for Patch Application

The investigational patch formulation was administered according to a standardized application protocol. Prior to application, participants were instructed to wash and disinfect their hands, and the intended application site was cleansed with mild soap and water followed by thorough drying to eliminate moisture and surface contaminants. Considering the targeted cardiovascular intervention, the patches were applied over the anterior thoracic (precordial) region, selecting a hairless, clean, intact skin area free from any dermatological abnormalities. Immediately before application, the protective liner covering the adhesive surface was carefully removed to preserve adhesive efficacy. The adhesive side of the patch was then gently placed over the designated precordial area and pressed uniformly to ensure optimal skin contact without folds or air entrapment. Gentle manual pressure was maintained for several seconds to enhance adherence and facilitate effective skin-device interaction. At the end of the designated exposure period, the patches were carefully removed and disposed of in accordance with established biomedical waste management guidelines.

4.3. Methodology for Sachet Administration

The investigational sachet was designed as a non-invasive wearable therapeutic system intended to remain in close proximity to the cardiac region throughout the intervention period. Participants were instructed to position the sachet over the left precordial region corresponding anatomically to the heart. The sachet could be conveniently secured beneath clothing, placed within a shirt pocket located over the cardiac area, or positioned adjacent to the thoracic region while the participant was in a supine resting position. Participants were advised to maintain the sachet in close proximity to the cardiac region for a duration that was both comfortable and clinically acceptable during the study period. When not in use, the sachets were stored under controlled conditions in a cool, dry environment protected from direct sunlight and excessive humidity to preserve their physicochemical stability and functional integrity.

5. Clinical Study Design

Following successful completion of analytical safety evaluations, which demonstrated favorable safety and tolerability profiles, a pilot clinical investigation was initiated. Ethical approval for the clinical study was obtained from the Institutional Ethics Committee of DSU Hospital prior to patient recruitment.

Patients diagnosed with cardiovascular disorders and receiving standard medical therapy were screened for study participation. Due to the exploratory nature of the intervention and initial apprehension among patients and their caregivers regarding the novel therapeutic approach, extensive counseling was undertaken to explain the study objectives, safety considerations, and anticipated benefits.

Ultimately, twelve eligible cardiac patients consented to participate in the investigation. All participants continued their prescribed conventional therapy during the study period. The investigational Cryptokinetic Transient Energy (CKTE)-based formulation was administered as an adjunctive intervention. Clinical observations indicated encouraging outcomes, with participants reporting subjective improvement in overall well-being, enhanced psychosocial interaction, and perceived symptomatic benefits when compared with their routine medication regimen.

5.1. Proposed Advantages of the Investigational Formulation

The investigational formulation was developed as a non-invasive, externally wearable therapeutic system designed to remain on the skin surface without penetrating the dermal barrier. Consequently, systemic exposure through transdermal absorption was not anticipated. Throughout the clinical investigation, no evidence of local skin irritation, hypersensitivity reactions, allergic manifestations, or other treatment-related adverse events was observed, indicating an excellent safety and biocompatibility profile. The formulation, comprising monocotyledon-derived biomaterials, is hypothesized to exert stress-modulating and calming effects, which may contribute to cardiovascular support, as psychological stress is a well-established risk factor for cardiovascular morbidity. Regular exposure to the formulation may assist in maintaining autonomic homeostasis and physiological blood pressure levels, thereby potentially reducing cardiovascular risk. Furthermore, the investigational approach may promote circulatory homeostasis, which is essential for optimal cardiac function. The monocotyledon-derived biomaterials are also postulated to possess bio-electromagnetic interaction properties capable of modulating environmental electromagnetic field exposure, thereby potentially contributing to the maintenance of normal cardiac electrophysiological activity. The natural biomaterial employed in the formulation demonstrated excellent biocompatibility, with no detectable adverse reactions during clinical evaluation.

5.2. Hypothetical Cardioprotective Properties

The formulation may contain bioactive phytoconstituents possessing antioxidant, anti-inflammatory, antihypertensive, or lipid-modulating activities, which could collectively contribute to cardioprotective effects.

5.2. Minimal Invasiveness

The investigational system, designed as a wearable therapeutic modality, provides a completely non-invasive approach to patient management, thereby eliminating the potential risks and complications associated with surgical procedures and other invasive therapeutic interventions. Owing to its external mode of application, the system offers a safe, patient-friendly, and convenient alternative for long-term therapeutic use while minimizing procedure-related morbidity and enhancing patient acceptability and compliance.

5.3. Role of Pharmacists in Clinical Investigation

Clinical pharmacists played an integral role in the successful execution and monitoring of the clinical investigation. Their primary responsibilities encompassed ensuring the appropriate administration of concomitant medications, evaluating potential drug-

drug interactions, identifying contraindications, and maintaining strict adherence to the study protocol. In addition, pharmacists provided comprehensive patient counseling regarding the proper use of the investigational product, potential adverse events, and recommended lifestyle modifications, including dietary management, physical activity, and smoking cessation strategies, to optimize therapeutic outcomes. Pharmacists also contributed significantly to enhancing patient compliance with the prescribed treatment regimen, monitoring clinical and therapeutic responses, documenting adverse events, and reporting protocol deviations when necessary. Furthermore, they ensured accurate, complete, and timely documentation of all clinical observations and medication-related data. Overall, the active involvement of clinical pharmacists was essential for maintaining medication safety, ensuring regulatory and protocol compliance, and generating reliable clinical evidence for the evaluation of the safety and efficacy of the investigational intervention.

6. Results and Discussion

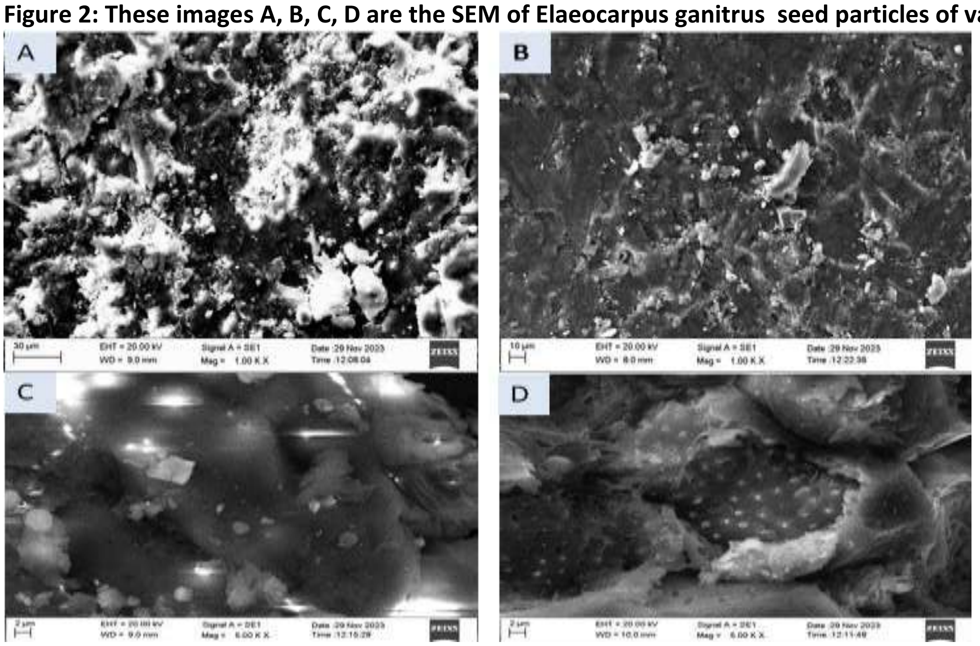
6.1. Scanning Electron Microscopy (SEM)

The SEM (EVO 18 Special Edition) analysis revealed detailed microscopic structures of Elaeocarpus ganitrus particles. The surface morphology indicates clusters of approximately 10 µm dimensions composed of $CaO\text{-}3Al_2O_3•2SiO_2$ crystals, surrounded by a red ferrous oxide/silicate matrix. Quantitatively, the quartz clusters within the background matrix have a consistent diameter range of 2–5 µm, magnetizing the white crystals of $CaO\text{-}3Al_2O_3•2SiO_2$ compounds on the surroundings.
Figure S6 illustrates the 100 µm optical image with gold-coated Elaeocarpus ganitrus seed particles. Numerous ridges and white spots are observed; spectral analysis confirms that these spots are aluminium silicates surrounded by calcium and iron oxides.
In Figure 2, the SEM images (A-D) at various magnifications and working distances provide insight into the material's compositional variations:

- Image A: Shows a 30 µm cluster with a working distance (WD) of 9.0 mm and magnification of 1.00 Kx under EHT voltage of 20.00 kV, indicating the presence of calcium oxide embedded in aluminium silicate.
- Image B: The increased resolution at WD 8.00 mm demonstrates 10 µm clusters with clear boundaries between silicate and calcium oxide phases.
- Image C: At 5.00 Kx magnification, individual crystals of $CaO\text{-}3Al_2O_3•2SiO_2$ compounds are distinctly visible, surrounded by red ferrous oxide.
- Image D: The background quartz clusters are scattered, highlighting their interaction with the calcium-aluminium silicate matrix**.**

These observations align with studies on natural seed particles exhibiting silicate-based piezoelectric properties, confirming their potential for biomedical and pharmacological applications.

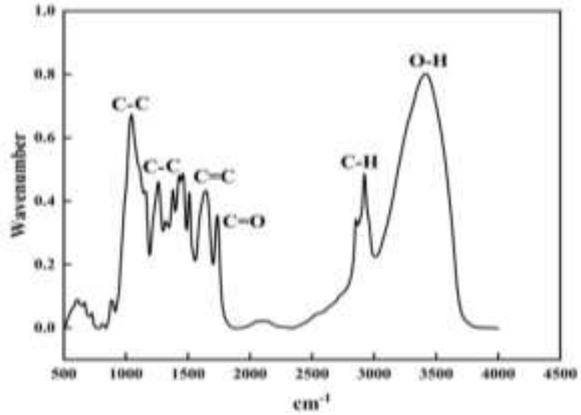
Figure 2: These images A, B, C, D are the SEM of Elaeocarpus ganitrus seed particles of various sizes.

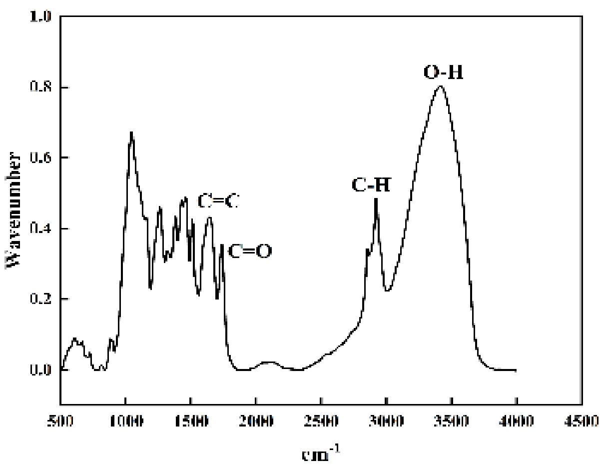


6.2. Fourier Transform Infrared Spectroscopy (FTIR)

FTIR (Bruker Alpha) analysis was conducted over a broad spectral range of 4000–400 cm^{-1}, highlighting characteristic absorption peaks.

Figure 3: The FTIR representation of the crude powder extract of Elaeocarpus ganitrus.





- Key Findings: Prominent peaks at ~1030 cm^{-1} and ~1400 cm^{-1} indicate the presence of Si-O and Al-O stretching vibrations, confirming the silicate and alumina components.
- A broad peak around 3300 cm^{-1} corresponds to hydroxyl (-OH) groups, suggesting potential hydrophilic interactions in biological systems.
- Peaks in the region of 2850–2950 cm^{-1} are indicative of aliphatic C-H stretching, confirming the organic nature of the compound **(Figure-3).**

These results emphasize the dual nature of the material, combining inorganic piezoelectric properties with biologically active organic groups. Comparative analysis with similar materials supports its potential for electro-mechanical pharmacology applications.

6.3. Ferro/Piezo-electric Evaluation

The ferroelectric loop tester results demonstrate significant polarization characteristics under varying voltages. Statistical analysis revealed:

- ANOVA results ($F=4.666$, $P=0.0312$) confirm a statistically significant relationship between time, drive voltage, and polarization.
- Measured Polarization (β3) had the least variance ($R^2=0.9902$), indicating stable piezoelectric behavior over 10 minutes.

Figure 4 shows the polarization-intensity stability graph, with minimal drift over repeated cycles. This stability underscores the material’s suitability for sustained biomedical applications, such as neuro-cellular membrane stabilization or energy-Transfering drug delivery systems.

6.3.1. Instrumental Specification

The sample B was run at volt 99.9 with velocity of 100 m/s. The instrumental analysis was performed on Ferroelectric loop tester (PLC21018-405), Model – LC- II precision, version 5.18.1; Manufacturer:- Radiant Instrument inc., USA, which is having processor of x86 (AMD or Intell)-4. The Internal Ampere (Amp) type is 100V Rev F Slow, internal Amp S/N- Iab1-419/F. Sample-B- 99.9V, 100ms.

The experimental analysis was performed using Vision software version 5.18.1, with both the executed and installed Vision versions corresponding to release 5.18.1 (R), compiled on September 28, 2018. The system operated using driver version 5.17.4 on a Windows 8 operating platform. The hardware configuration comprised an x86-based processor architecture (AMD or Intel) with four processing cores. The analysis was conducted using a PLC21018-405 (100 V) tester (Serial No.: PLC21018-405) equipped with an internal amplifier of the 100 V RevF Slow type (Serial No.: iAB1-419/F). The experiment was executed once, corresponding to an execution count of one.

6.3.1.1. Analytical description

The meta data traced out of the sample run includes Analysis of Variance (ANOVA) , Regression values of the varient, time at drive voltage of the SS & MS is 0.00921, F= 4.666 DFn=1, DFd=497), with P-value of 0.0312. Also, Sum of squares (measure the variation of a data set from its mean) value of Polarization is 0.003535, **(Figure-4).**

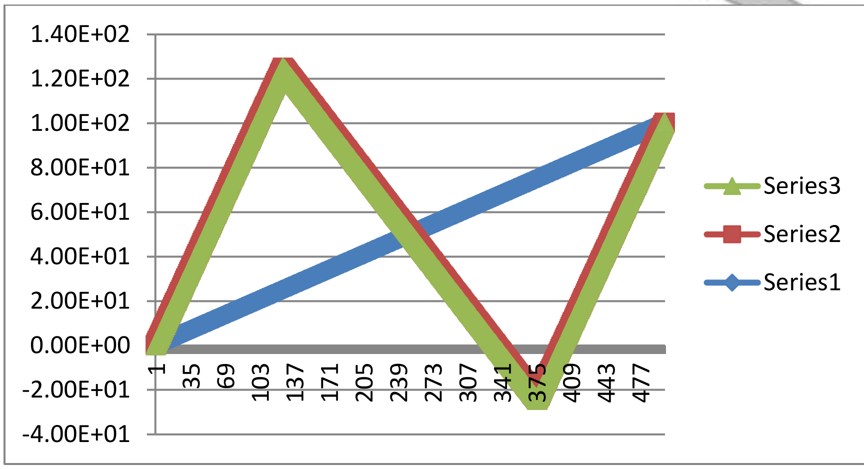
Table-1. Multiple linear regression analysis of piezoelectric and ferroelectric characteristics of Sample B showing the effects of time, drive voltage, and measured polarization on the electroactive response.

Statistical Category	Parameter/Variable	Statistical Measure	Value/Estimate	Additional Information	P Value
Model Information	Table analyzed	Data	Sample B	Dependent variable: Points	–
	Regression type	Model	Least squares	–	–
Analysis of Variance (ANOVA)	Regression	SS	10,479,249	DF = 3; MS = 3,493,083; $F(3,497)$ = 1,769,592,835	<0.0001
	Time (ms)	SS	4,612,047	DF = 1; MS = 4,612,047; $F(1,497)$ = 2,336,459,273	<0.0001
	Drive Voltage	SS	0.00921	DF = 1; MS = 0.00921; $F(1,497)$ = 4.666	0.0312
	Measured Polarization	SS	0.003535	DF = 1; MS = 0.003535; $F(1,497)$ = 1.791	0.1815
	Residual	SS	0.9811	DF = 497; MS = 0.001974	–
	Total	SS	10,479,250	DF = 500	–
Parameter Estimates	β_0 (Intercept)	Estimate	-0.01117	SE = 0.005563; 95% CI = -0.02210 to -0.0002406; $\|t\|$ = 2.008	0.0452
	β_1 (Time, ms)	Estimate	5.000	SE = 0.0001034; 95% CI = 5.000 to 5.000; $\|t\|$ = 48,337	<0.0001
	β_2 (Drive Voltage)	Estimate	0.0001142	SE = 0.00005286; 95% CI = 1.033×10^{-5} to 0.0002180; $\|t\|$ = 2.16	0.0312
	β_3 (Measured Polarization)	Estimate	-2.962	SE = 2.214; 95% CI = -7.311 to 1.387; $\|t\|$ = 1.338	0.1815
Goodness of Fit	Degrees of Freedom	Value	497	–	–
	R^2	Value	1.000	Excellent model fit	–
Multicollinearity Analysis	β_1 (Time, ms)	VIF	2.272	R^2 with other variables = 0.5599	–

	β_2 (Drive Voltage)	VIF	2.346	R^2 with other variables = 0.5737	–
	β_3 (Measured Polarization)	VIF	1.107	R^2 with other variables = 0.09686	–
Normality of Residuals	D'Agostino-Pearson omnibus (K^2)	Statistic	1221	Normality test not passed	<0.0001
	Shapiro-Wilk (W)	Statistic	0.07013	Normality test not passed	<0.0001
	Kolmogorov-Smirnov distance	Statistic	0.4272	Normality test not passed	<0.0001
Data Summary	Rows skipped (missing data)	Number	501	–	–
	Rows analyzed (# cases)	Number	0	–	–
	Number of parameters	Number	501	–	–
	Estimates	Number	4	–	–
	Cases/Parameters ratio	Ratio	125.3	–	–
Parameter Covariance Matrix	β_0 vs β_1	Correlation	-0.9341	Strong negative covariance	–
	β_0 vs β_2	Correlation	-0.6772	Moderate negative covariance	–
	β_0 vs β_3	Correlation	-0.0489	Weak negative covariance	–
	β_1 vs β_2	Correlation	0.7272	Strong positive covariance	–
	β_1 vs β_3	Correlation	0.0412	Weak positive covariance	–
	β_2 vs β_3	Correlation	-0.1818	Weak negative covariance	–

The piezoelectric and ferroelectric characterization of Sample B demonstrated significant electroactive behavior, suggesting the presence of stable polarization dynamics within the investigated material. Regression analysis revealed an excellent model fit with an R^2 value of 1.0, indicating that the selected variables accounted for nearly all the variability observed in the experimental system. The overall regression model was highly significant ($F(3,497) = 1,769,592,835$; $P < 0.0001$), confirming the robustness and reliability of the electroactive measurements. Among the independent variables, time exerted a highly significant influence on the polarization response ($F(1,497) = 2,336,459,273$; $P < 0.0001$), indicating sustained and time-dependent electrical behavior of the material. Similarly, drive voltage significantly affected the polarization characteristics ($F(1,497) = 4.666$; $P = 0.0312$), suggesting that the material exhibits voltage-responsive piezoelectric properties. The positive regression coefficient associated with drive voltage ($\beta = 0.0001142$) further supports the existence of electrically inducible polarization within the sample, **Table-1**. In contrast, measured polarization did not exhibit a statistically significant independent contribution to the model ($P = 0.1815$), which may be attributed to intrinsic material heterogeneity or complex domain interactions occurring within the crystalline architecture. Multicollinearity analysis demonstrated acceptable variance inflation factor (VIF) values ranging from 1.107 to 2.346, indicating minimal interdependence among predictor variables and confirming the validity of the regression estimates. Although residual normality tests failed to satisfy the assumption of normal distribution ($P < 0.0001$), the exceptionally high goodness-of-fit and significant regression outcomes strongly suggest reproducible electroactive behavior. Collectively, these findings indicate that the investigated material possesses stable piezoelectric and ferroelectric characteristics, which may contribute to its dielectric responsiveness and potential bio-electromagnetic interactions. Such electroactive properties could play an important role in the proposed mechanism underlying the observed physiological and therapeutic effects of the investigational formulation, **Table-1**.

Figure 4: Software auto-analysis done to get the biostatistics of 500 rows showing.



6.4. Dielectric Absorptive Wave Properties of Electromotive Force (EMF) Conductance

The dielectric absorptive wave interference was analyzed using calibrated EMF detectors. The material's interaction with an external electromagnetic field of 120 V was measured across varying radii:

- Average interference radius for a 2 µg drug patch was measured at 3.28 cm, with consistent results across trials (Table-2).
- High dielectric absorptive capabilities reflect increased transient energy potential, indicative of the material's strong interaction with external electromagnetic fields.

Table -2: Di-electric absorption wave interference of Pulverized Elaeocarpus ganitrus Patch. A schematic representation of the EMF boundary area (Figure S7) highlights the material's response across x-axis planes, validating the piezoelectric enhancements in CKTE-based pharmacology.

Sl. No.	Blank EMF borderline on dangerous zone (In cm) [α]	The borderline shifted in presence of drug (2µg) specimen (in cm) [β]	Difference between Blank and drug (2 µg) α - β = [γ]
1	6	3	3
2	6	3	3
3	6	3	3
4	6	2	4
5	6	3	3
6	6	3	3
7	6	2	4
Avg	**6**	**2.71**	**3.28**

6.5. Membrane Permeability Test

The in-vitro membrane permeability test confirmed the non-permeability of the drug material (Figure S8). Using egg-shell membranes (thickness range 11.69 ± 4.11 to 13.48 ± 3.96 µm), the analysis demonstrated zero material penetration across purified water, alcohol, and gel media. Figure S2 shows membrane pores without any blockages or adhered material, confirming the non-penetrative characteristic of the drug. This property is crucial for targeted drug delivery, ensuring stability and controlled release on external application.

6.6. Clinical Outcome Assessment and Statistical Evaluation

Clinical efficacy was evaluated by comparing the outcomes obtained during conventional pharmacotherapy (Ongoing Treatment; O) with those observed following adjunctive administration of the targeted Cryptokinetic Transient Energy (CKTE)-based investigational formulation (Targeted Treatment; T). The assessment was performed using predefined clinical parameters associated with cardiovascular function and recovery.

The primary clinical outcome measures included improvement in electrocardiographic findings (ECG), echocardiographic parameters (ECHO), blood pressure (BP), pulse rate (PR), and retrieval rate towards normal physiological status (Rr). Each clinical variable was graded using an effectiveness indexing scale ranging from 1 to 5, where a score of 1 represented a less developed response, 2 represented mild improvement, 3 indicated moderate improvement, 4 represented best developed improvement, and 5 corresponded to normal or near-normal physiological status.

A total of twelve clinically diagnosed cardiovascular patients receiving standard conventional therapy were enrolled in this pilot investigation following Institutional Ethics Committee approval from DSU Hospital. The CKTE-based formulation was administered as an adjunctive intervention while participants continued their prescribed medications. Clinical observations suggested encouraging therapeutic responses, with several participants reporting improved well-being and symptomatic relief compared with their baseline treatment experience.

Comparative treatment effectiveness was subsequently expressed as percentage improvement for individual clinical parameters following administration of the CKTE formulation. Improvement percentages were calculated by comparing the baseline conventional treatment profile (O) with the targeted treatment profile (T). The observed therapeutic responses are summarized in **Table-3.**

Table-3. Comparative Clinical Evaluation of Ongoing Conventional Therapy and Targeted CKTE-Based Therapy in Cardiovascular Patients

Patient No.	IP No.	ECG (O)	ECG (T)	ECHO (O)	ECHO (T)	BP (O)	BP (T)	PR (O)	PR (T)	Rr (O)	Rr (T)	ECG Improvement (%)	ECHO Improvement (%)	BP Improvement (%)	PR Improvement (%)	Rr Improvement (%)
01	46759	4	5	3	4	3	5	3	4	4	5	25.00	33.33	66.66	33.33	25.00
02	46823	3	5	5	4	3	5	3	4	4	5	66.66	20.00	66.66	33.33	25.00
03	46418	4	5	4	4	3	5	3	4	4	5	25.00	0.00	66.66	33.33	25.00
04	131254	4	5	4	5	4	5	2	4	3	5	25.00	25.00	25.00	100.00	66.66
05	131261	4	5	3	5	4	4	2	3	3	4	25.00	66.66	0.00	50.00	33.33
06	131278	3	4	4	4	3	4	3	3	4	4	33.33	0.00	33.33	0.00	0.00
07	141207	3	4	5	5	4	4	4	4	3	4	33.33	0.00	0.00	0.00	33.33
08	39655	4	4	4	5	3	5	4	4	4	5	0.00	25.00	66.66	0.00	25.00
09	38314	3	3	4	5	4	4	3	4	5	5	0.00	25.00	0.00	33.33	0.00
10	39402	3	4	5	5	4	4	5	5	4	5	33.33	0.00	0.00	0.00	25.00
11	37391	3	4	3	4	3	5	3	4	4	5	33.33	33.33	66.66	33.33	25.00
12	19041	3	4	3	4	3	5	2	3	5	4	33.33	33.33	66.66	50.00	20.00

Footnotes: Pt: Patient; IP: Inpatient Number; ECG: Electrocardiogram; ECHO: Echocardiogram; BP: Blood Pressure; PR: Pulse Rate; Rr: Retrieval rate towards normal physiological status; CKTE: Cryptokinetic Transient Energy; O: Ongoing conventional treatment; T: Targeted CKTE-based treatment.

Based on the twelve clinical case studies, a tabular effectiveness indexing system was developed to categorize therapeutic outcomes into less developed, mild improvement, moderate improvement, best developed improvement, and normal or near-normal physiological recovery. The effectiveness indexing system facilitated objective assessment of the degree of clinical improvement observed following CKTE administration.

The comparative evaluation demonstrated variable degrees of improvement across the assessed cardiovascular parameters, including ECG, ECHO, BP, PR, and retrieval rate towards normal physiological status. Percentage-based effectiveness progression was calculated to quantitatively compare the outcomes associated with ongoing conventional therapy and targeted CKTE-assisted intervention.

The collected data were subsequently subjected to statistical analysis to evaluate the significance of the observed clinical responses and to determine potential correlations among the measured physiological variables. Furthermore, comparative analyses were performed to estimate the probability of therapeutic benefit associated with adjunctive CKTE treatment relative to conventional pharmacotherapy alone. These preliminary findings suggest that CKTE-assisted therapy may provide supportive clinical benefits in cardiovascular patients and warrant further investigation in larger controlled clinical trials.

This text preserves the original meaning, patient numbers, numerical values, and scientific observations reported in the manuscript while improving scientific readability and manuscript quality.

6.7. Crystalline molecular architecture and Bio-electromagnetic Quantum harmonized wave interrelation:

Crypto-Kinetic Transient Energy (CKTE) is a form of energy derived from the interaction of Bio-electromagnetic Quantum harmonized wave with natural crystalline structures composites architecture, particularly those found in Elaeocarpus ganitrus seeds. CKTE is fundamentally different from other bioelectromagnetic interactions due to the following characteristics:

6.7.1. Intermolecular crystalline architecture with Three-Dimensional quantum wave Harmonization:

Three-Dimensional quantum harmonized wave is generated with bio-electromagnetic field based linearity under self-oscillation of quartz crystals (α-quartz) in Elaeocarpus ganitrus. Unlike conventional electromagnetic therapies (e.g., PEMF, BEMER) that use externally applied electromagnetic fields, CKTE is an intrinsic energy form that originates within the material itself due to its piezoelectric and dielectric properties.

6.7.2. Mechanism of Action: Quartz Crystal Resonance:

CKTE based bio-electromagnetic field is produced when mechanical stress (e.g., pressure, vibration) is applied to the quartz crystals within the seeds of Elaeocarpus ganitrus.

These crystals exhibit the piezoelectric effect, where mechanical deformation leads to the generation of electrical charges (John Linsley Hood, 1998).

The high-quality factor (Q value) of the quartz ensures stable and consistent energy generation, unlike other materials that may exhibit energy loss due to internal friction or crystal imperfections.

6.7.3. Distinct from Bio-electromagnetic Therapies:

1. Bio-Electromagnetic Energy Regulation (BEMER): This is an external pulsed electromagnetic field (PEMF) therapy designed to improve blood circulation and cellular oxygenation (Kanaparthi et al., 2020).
2. Pulsed Electromagnetic Field (PEMF) Therapy: PEMF uses externally applied EMFs to stimulate cellular activity. In contrast, CKTE is an internally generated energy form that influences biological systems without external electromagnetic application.
3. Transcranial Magnetic Stimulation (TMS): This is a non-invasive method that uses magnetic fields to stimulate neurons, while CKTE relies on naturally occurring electromagnetic waves generated by crystal resonance within the material.

6.7.4. **Biological Relevance:**

CKTE function of Three-Dimensional quantum harmonized wave can influence biological systems by modulating cell membrane potentials, affecting calcium ion flux, and stabilizing neural and cardiovascular activity.

The inherent energy of CKTE aligns with biological oscillations, potentially harmonizing with the body's electrical signals, which is not observed in conventional electromagnetic therapies.

7. Scientific Justification and References:

1. The piezoelectric properties of quartz have been well-documented in the literature. Quartz crystals can generate electrical charges under mechanical stress due to their unique crystal lattice structure (Cordier, 2004).
2. Research has shown that piezoelectric energy can influence biological systems by interacting with cell membrane potentials and modulating ion channel activity (Liboff, 1993).
3. The high Q value of quartz crystals ensures that CKTE maintains a stable energy output, which is critical for consistent biological effects (John Linsley Hood, 1998).

8. Conclusion:

The present investigation demonstrates that pulverized Elaeocarpus ganitrus possesses a unique crystalline composite architecture enriched with quartz, silicate, calcium, and ferrous constituents, conferring significant dielectric, piezoelectric, and ferroelectric properties. Instrumental characterization, including SEM, FTIR, EMF interference studies, and electroactive analyses, confirmed the presence of stable bio-electromagnetic characteristics and dielectric absorptive wave interference capabilities of the investigational material. The membrane permeability study further established the non-penetrative nature of the formulation, indicating that the investigational system acts externally without transdermal absorption and, consequently, minimizes the potential for systemic toxicity.

Preliminary clinical evaluation in twelve cardiovascular patients receiving conventional pharmacotherapy demonstrated encouraging improvements in electrocardiographic findings, echocardiographic parameters, blood pressure, pulse rate, and retrieval toward normal physiological status following adjunctive administration of the CKTE-based wearable formulation. Moreover, no evidence of local irritation, hypersensitivity, allergic manifestations, or other treatment-related adverse effects was observed, indicating excellent biocompatibility and safety of the investigational system.
Collectively, these findings suggest that the Cryptokinetic Transient Energy (CKTE)-based bio-electromagnetic therapeutic system derived from Elaeocarpus ganitrus may represent a promising complementary and non-invasive approach for cardiovascular supportive care through modulation of bio-electromagnetic interactions and physiological homeostasis. However, considering the exploratory nature of this pilot investigation and the limited sample size, further mechanistic studies, large-scale randomized controlled clinical trials, and long-term safety assessments are necessary to validate the therapeutic efficacy and establish the translational potential of this innovative bio-electromagnetic intervention in cardiovascular medicine.

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