THE RATIONALE BEHIND HT-11 BY SAFEU SUSTAINABILITY & AGRI-NET-ZERO PATHWAYS PVT. LTD.

SAFE-U's Core Mission is rooted in promoting human health through sustainable food systems—producing safe, toxin-free, and nutritionally secure food. It is a dissemination arm of Inhana Organic Research Foundation (IORF), transferring cutting-edge technologies like Novcom Composting Technology and Inhana Rational Farming (IRF) technology to the global market. Health and sustainability are interlinked, and SAFE-U bridges this connection.

Extending the Mission to Medicine: HT-11 aligns with SAFE-U's foundational philosophy: to research, develop, and disseminate safe, effective solutions that support human health—whether through agriculture or medicine.

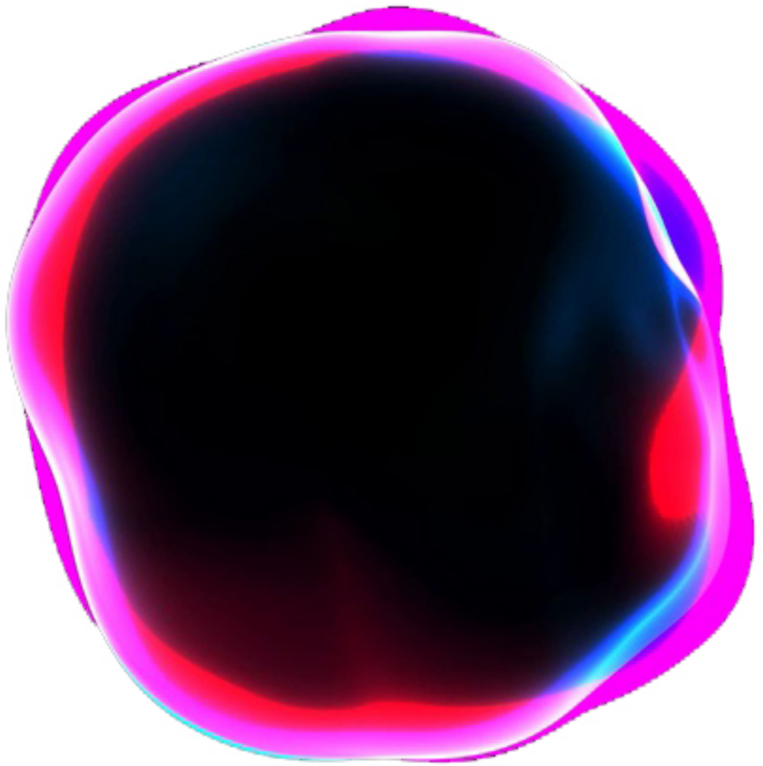
Leadership with a Medical Vision: The initiative is led by SAFE-U Director, Ms. Adrija Das Biswas, currently pursuing a Doctoral Program in Immunohematology and Medical Oncology at Medical College Kolkata. Her academic background and research expertise provide the scientific foundation for the HT-11 project.

A Science-Driven Exploration: HT-11 is being scientifically developed to study its formulation, shelf life, delivery models, and overall potential as a health-promoting agent—carrying forward SAFE-U's tradition of evidence-based innovation.

HT-11

Bridging Ancient Wisdom with Modern Medicine for Bleeding Control and Wound Recovery

TRAUMATIC HEMORRHAGE: SCOPE AND SIZE OF THE PROBLEM



CLOSING THE BLEEDING EDGE: TACKLING HEMOSTASIS AND WOUND HEALING

1. Global Trauma and Hemorrhage Crisis

- Accidental/Traumatic injuries are the leading cause of premature deaths and disability worldwide, accounting for **9%** of global deaths.
- India faces a high burden of injuries, with road traffic accidents as the second leading cause of death and disability.
- **0.15 million deaths annually in India** due to accidental injuries/road traffic accidents, representing 11% of global accident-related deaths.
- **Over 20% of the world's trauma deaths occur in India**, where injuries are a significant public health concern.

2. Traumatic Hemorrhage: The Leading Preventable Cause of Death

- **Traumatic hemorrhage** accounts for **35% of global mortality** from injuries.
- The **leading cause of death** in trauma cases is **uncontrolled hemorrhage**—which is **preventable**.
- **50% of these deaths occur before reaching a hospital**—underscoring the **time-sensitive nature** of hemorrhage control.

Systemic administration of hemostatic agents requires **trained personnel**, limiting their use in **combat and prehospital settings**.

Current products are limited by:

- **Risk of infection**
- **Immunogenicity** (immune reactions)
- **Tissue damage**
- **High costs**
- **Short shelf life**
- **Storage under specific conditions**.

BAND-AIDS WITH BAGGAGE: WHAT ARE THE **CHALLENGES** WITH CURRENT HEMOSTATIC AGENTS?

A Revolutionary Indigenous Hemostatic Solution

HT-11

Integrate **ancient Indian wisdom** with **modern biomedical science**?

Serve as an **indigenous technology**, built on **Energy–Element Activation** — a fusion of *Pancha Mahabhuta* with biochemical clotting mechanisms?

Support **first responders**, **rural & urban trauma care**, **military**, and **disaster response protocols**?

Act locally at the site of application, avoiding systemic absorption?

Cause no systemic toxicity and no interference with systemic coagulation pathways?

Trigger both intrinsic and extrinsic coagulation cascades for rapid fibrin clot formation?

Enhance both primary (platelet aggregation) and secondary (coagulation cascade) hemostasis?

Be made of potentized biologically activated herbal extracts with proven pro-coagulant and anti-microbial properties?

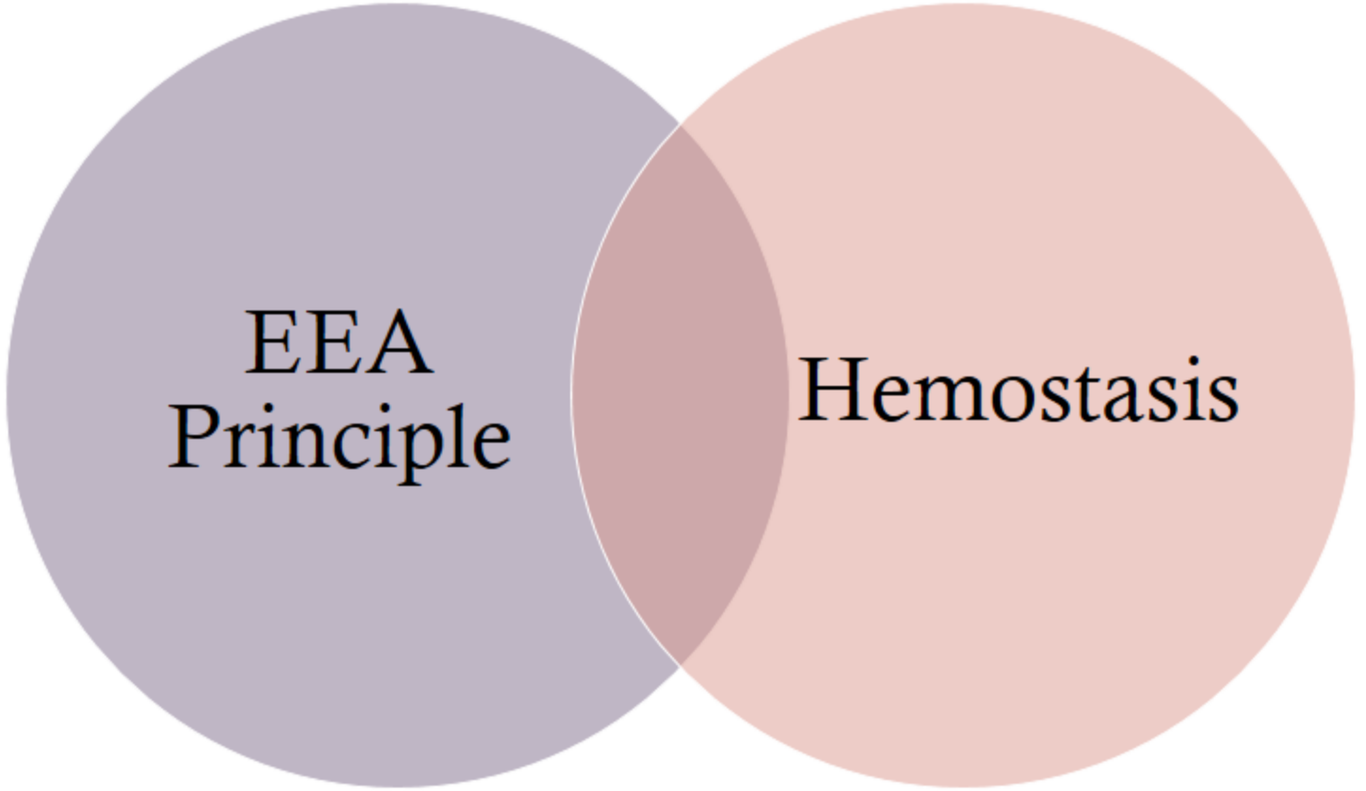
Require minimal infrastructure, ideal for use in the field?

Be safe, sustainable, and ethically formulated?

VISION

To position India as a global leader in indigenous, scientifically validated health technologies through a new class of biotherapeutics that are safe, fast, effective, and accessible to all. HT-11 is just the beginning of a broader, scalable platform.

MECHANISM OF ACTION

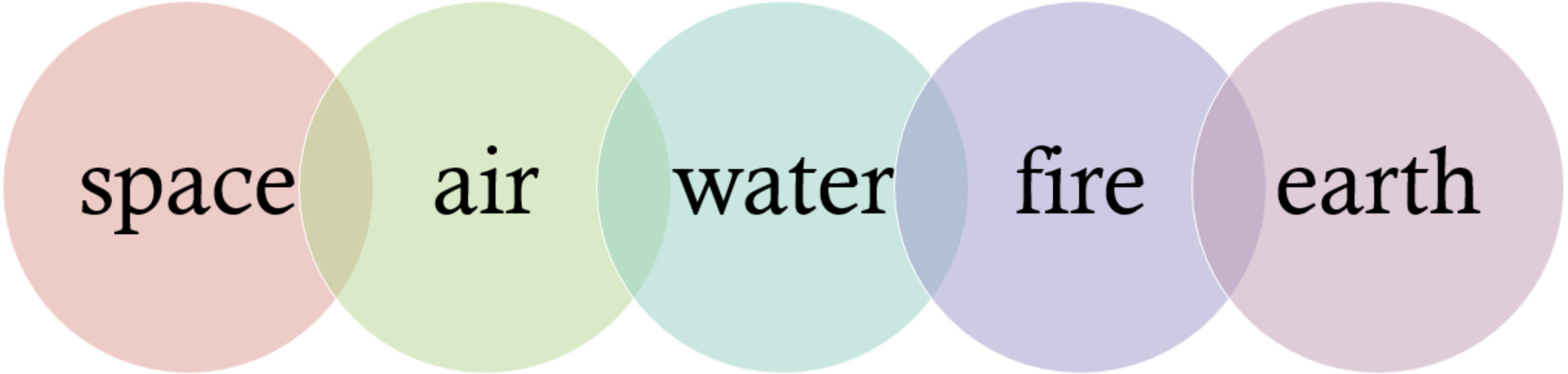


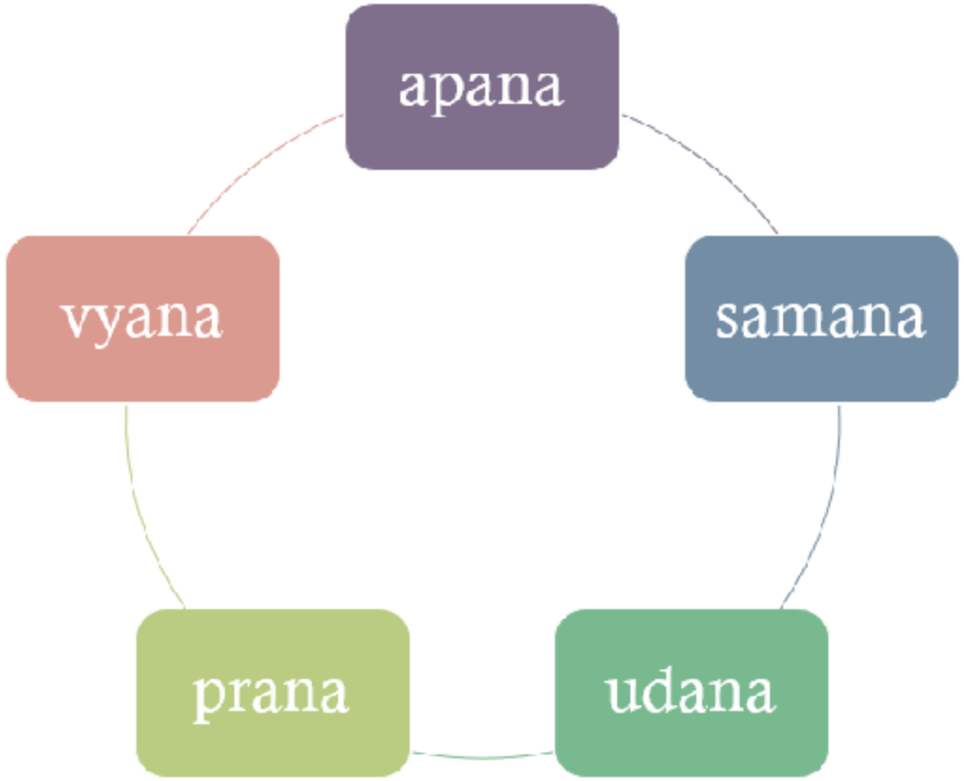
WHAT IS EEA?

Energy Element Activation Principle

Deeply rooted in India's ancient Vedic wisdom, drawing directly from the foundational concepts of Pancha Mahabhuta (the five great elements) and Pancha Prana (the five life forces), which together offer a holistic framework for understanding and harmonizing the body's natural energies.

5 BASIC ELEMENTS PRESENT IN EVERY NATURAL INANIMATE AND ANIMATE BEING IN DIFFERENT PROPORTIONS





We are alive because a cosmic energy called **Prana** flows through us and has 5 functions


5 basic elements
5 life-forces
keep our bodies healthy

THEREFORE

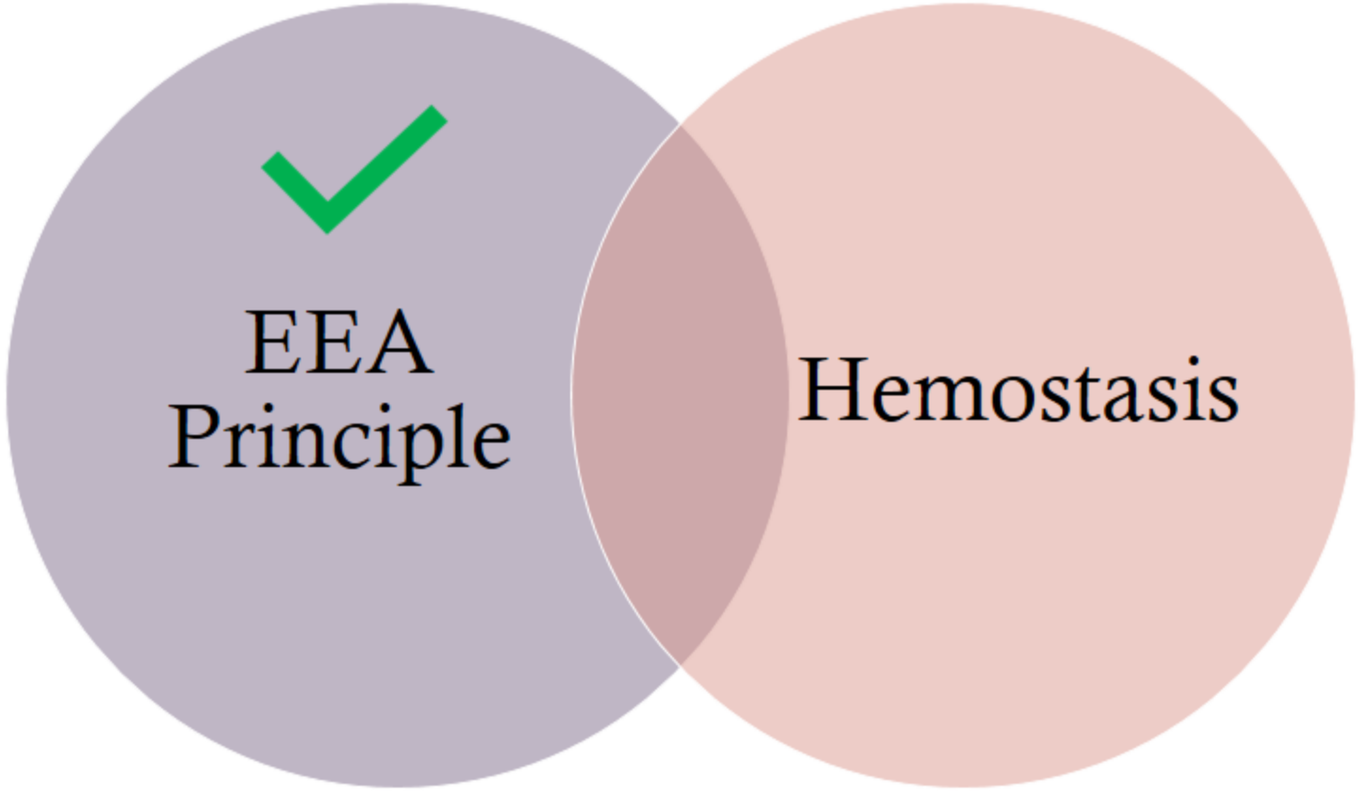
IMBALANCE IN ANY = WE ARE SICK

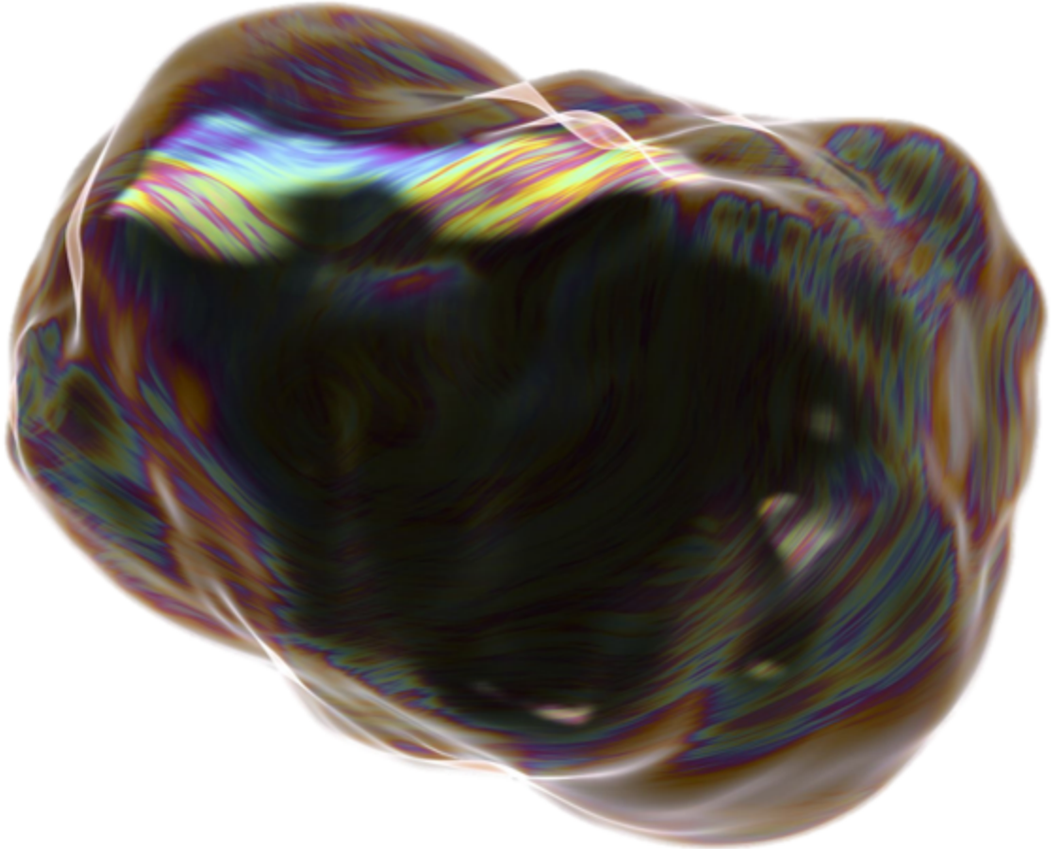
Instead of just trying to treat the symptoms, the goal is to restore balance and help the body heal itself naturally.

HOW TO DO THAT?

- Selection of specific plants on specific day and time
- Alcoholic extraction from specific plant parts
- Energisation isolation of energy components
- Potentization – release of bound energy in order of 10^3 to 10^4 times
- Combination of activated, potentized and energized extract

MECHANISM OF ACTION





HEMOSTASIS

- The process of haemostasis, particularly following a topical injury, involves a complex interplay between cellular elements and plasma proteins.
- While significant progress has been made in understanding the coagulation cascade, certain aspects, especially within the intrinsic pathway, remain incompletely elucidated.

INTRINSIC PATHWAY AND FACTOR XII

The intrinsic pathway is initiated by the activation of Factor XII (Hageman factor), which subsequently activates a cascade involving prekallikrein and high molecular weight kininogen.

Interestingly, deficiencies in Factor XII, prekallikrein, or high molecular weight kininogen do not typically result in bleeding disorders, suggesting that while these factors are crucial for in vitro coagulation assays, they may play a less critical role in physiological haemostasis .

THAT POINT IS HIGHLY RELEVANT BECAUSE IT HIGHLIGHTS A **CRITICAL DISCREPANCY BETWEEN LABORATORY-BASED UNDERSTANDING AND ACTUAL BIOLOGICAL FUNCTIONING IN THE BODY** - A KEY THEME WHEN PROPOSING ALTERNATIVE OR COMPLEMENTARY FRAMEWORKS LIKE THE *ENERGY - ELEMENT ACTIVATION PRINCIPLE*.

Modern drugs often try to "force" a certain reaction (like clotting), sometimes at the cost of systemic risks (like thrombosis).

HT 11, rooted in elemental balance, **stimulates physiological readiness** rather than overriding natural controls—highlighted by how **Factor XII's absence doesn’t derail haemostasis**, suggesting that the body has **redundant or compensatory pathways**.

Factor XII, prekallikrein, and HMW kininogen are integral to the intrinsic pathway in *in vitro* (test tube) systems, yet their absence in humans **does not consistently cause bleeding**.

This suggests that our classical coagulation cascade model **may not fully explain physiological haemostasis**, especially for injury-related, localized responses.

If some components that are critical in theory (or lab models) aren't essential in real-life clotting, it **opens the door for alternative perspectives.**

HT 11 doesn't just aim to push forward the classical clotting pathway; instead, it works by **energizing and harmonizing multiple elements and functions** (e.g., platelets, prothrombin, circulation).

PLATELET ACTIVATION AND SHAPE CHANGE

Resting platelets exhibit a discoid shape, maintained by a circumferential microtubule ring.

Upon activation, there is a rapid reorganization of the cytoskeleton, leading to a spherical shape that facilitates adhesion and aggregation at the site of vascular injury.

This morphological transformation is driven by intracellular calcium mobilization and actin filament remodeling .

ROLE OF FACTOR VIII IN COAGULATION

01

Factor VIII circulates in plasma bound to von Willebrand factor (vWF) in an inactive form.

02

Upon activation by thrombin or Factor Xa, Factor VIII dissociates from vWF and undergoes proteolytic cleavage, resulting in the active cofactor, Factor VIIIa.

03

Factor VIIIa then forms a complex with activated Factor IX (FIXa) on phospholipid surfaces, significantly enhancing the activation of Factor X to Xa .

THE REMAINING CASCADE

- Intrinsic tenase complex (VIIIa + IXa + Ca^{2+} + phospholipids) activates Factor X to Factor Xa
- Factor Xa binds Factor Va to form the prothrombinase complex on the platelet membrane
- Prothrombinase complex converts prothrombin (Factor II) into thrombin (Factor IIa)
- Thrombin converts fibrinogen into fibrin monomers
- Thrombin also activates Factor XIII to Factor XIIIa
- Factor XIIIa crosslinks fibrin to stabilize the clot
- Thrombin further activates platelets, amplifying aggregation
- Additional thrombin activates Factors V, VIII, and XI — reinforcing the cascade
- A stable fibrin-platelet clot forms, sealing the injury site
- Once the vessel is repaired, fibrinolytic mechanisms (like plasmin activation) dissolve the clot to restore normal flow

LETS UNDERSTAND HEMOSTASIS THROUGH THE LENS OF EEA PRINCIPLE

01

We can match each part of the process to one of the five elements:

02

Blood is connected to the **Water element**.

03

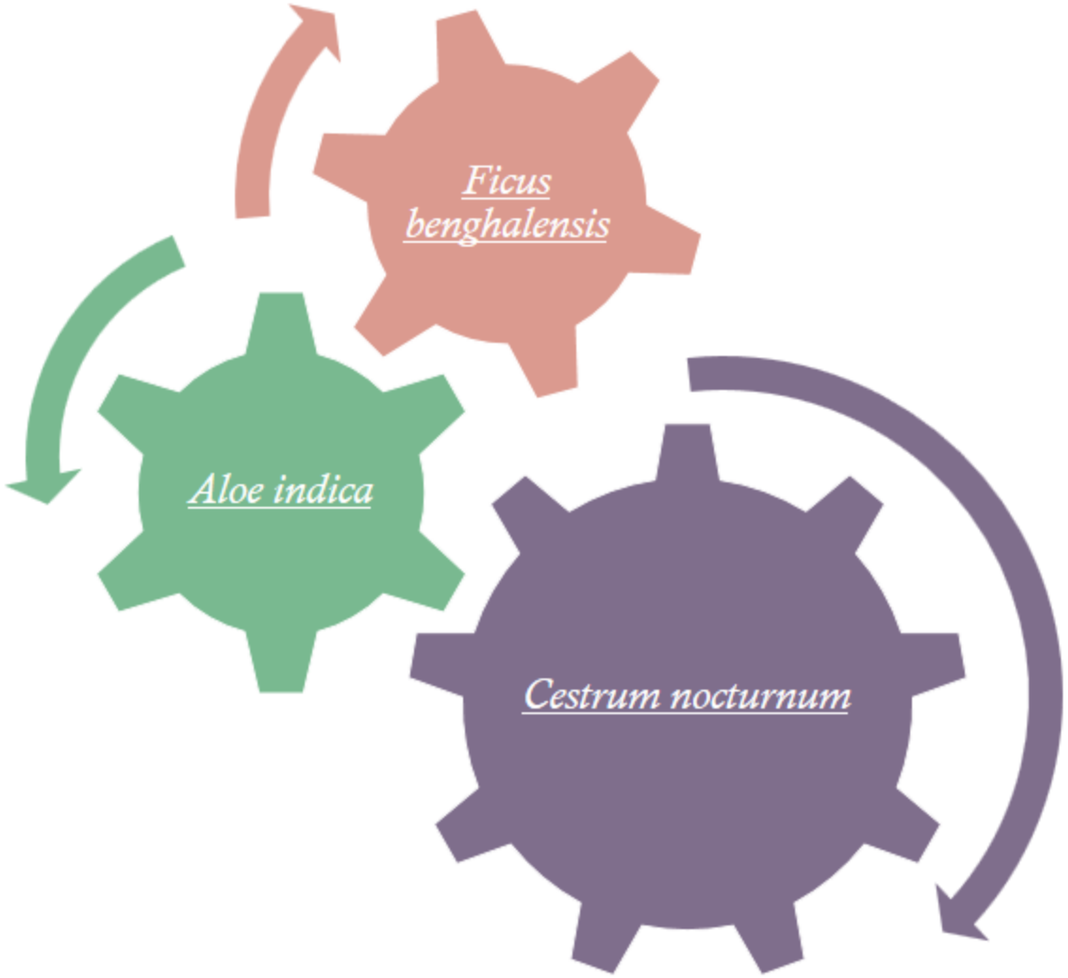
Platelets are linked to the **Subtle Earth element**.

04

Tissue veins are linked to the **Gross Earth element**.

05

Circulation is connected to the **Space element**.



Energizes and **activates** the elements in a balanced way to help blood clot where it's needed

HT-11

A TOPICAL HEMOSTAT OF HERBAL ORIGIN

HOW?

Blood (Water Element): HT 11 enhances the activation of prothrombin and fibrinogen, essential for clot formation.

Platelets (Subtle Earth Element): It promotes platelet aggregation, crucial for the initial plug formation.

Tissues and Blood Vessels (Gross Earth Element): HT 11 stimulates thromboplastin activity, initiating the coagulation cascade.

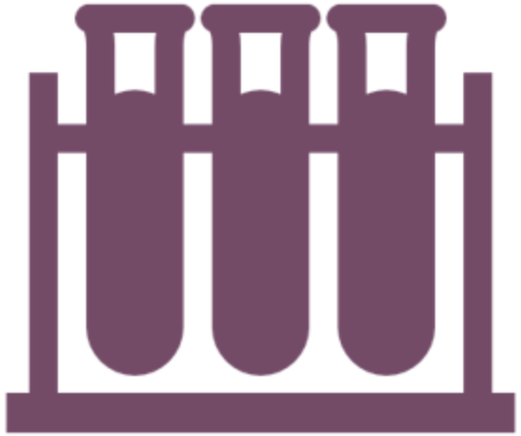
Circulation (Space Element): It modulates vascular tone and ensures the targeted delivery of clotting factors to the injury site while mitigating the effects of natural anticoagulants like Antithrombin III.

THE RESEARCH TILL NOW…

RESEARCH SUMMARY TABLE: DEVELOPMENT AND EVALUATION OF HT-11

Area	Details
Initial Efficacy Study	**Date**: 18 March 2002 **Location**: Life Pharmaceuticals lab **Subject**: RAM (animal model) **Method**: Ear lobe pricked, HT-11 applied **Outcome**: Clotting time reduced from 61s to 42s (↓31.14%) **Observation**: No side effects; consistent results across three trials
Confirmation & Communication	**Date**: 26 March 2002 **Person**: Suman Majumdar (R&D, Life Pharmaceuticals) **Content**: Confirmed efficacy, suggested further studies (toxicity, animal models, clinical trials)
Formulation Stability	**pH Pre-Autoclave**: 6.13 **pH Post-Autoclave**: 5.8 **Stability**: HT-11 remained effective and stable post-autoclaving
Human Case Studies (Topical Application)	**Total Cases**: 10 (Age range: 6 to 65 years) **Wound Types**: Cuts, bruises, deep wounds, abrasions **Dosage**: 0.1–1.0 ml **Outcome**: Bleeding stopped within seconds to a minute in all cases; healing observed within 2–7 days; no pain or scarring
Key Inferences (Human Models)	• Rapid hemostasis across age groups and wound types • Safe for children and elderly • Healing promoted with no residual marks • Indicates potential for use in first-aid and emergency scenarios
Antimicrobial Activity Study	**Institution**: Jadavpur University **Form**: Alcoholic extract of HT-11 **Bacterial Strains**: 14 tested **Minimum Inhibitory Amount (MIA)**: 3 strains inhibited at 0.5 ml; 11 at 1.0 ml **Conclusion**: Broad-spectrum antibacterial activity confirmed

EVALUATION OF SAFETY AND EFFICACY OF HT-11 IN EXPERIMENTAL ANIMALS



Preclinical Study (July – September 2002)
Ethical Approval: Medical College Kolkata (22nd July 2002)
Study Duration: 3 months
Study Locations: NRS Medical College, Calcutta National Medical College

EVALUATION OF SAFETY AND EFFICACY OF HT-11 IN EXPERIMENTAL ANIMALS

Key Findings:

- **Safety Profile**: HT-11 exhibited **no toxicity** in local administration.
- **Wound Healing**: Showed **moderate acceleration of wound healing**.
- **Hemostatic Effect**: Demonstrated significant **blood-clotting potential**.
- **Antimicrobial Properties**: Moderate antimicrobial activity was observed.

Conclusions:

- HT-11 was found to be **safe** for local use and **effective** in promoting wound healing and coagulation in animal models.
- **Future Studies Needed**:
  - Further research to understand the **mechanism of action** related to coagulation physiology.
  - **Increased sample size** for better statistical significance in subsequent trials.
  - **Pilot clinical trials** recommended, especially focusing on patients with hemorrhagic conditions.
  - **Long-term observation** required to assess **scar formation** in animal models.

CLINICAL AND HISTOPATHOLOGICAL STUDY OF HT-11 TO EVALUATE ITS WOUND HEALING PROPERTIES

- **Ethical Approval**: Medical College Kolkata, Ethical Committee (23rd October 2002)
- **Study Duration**: **6 months (November 2002 – October 2003)**
- **Study Locations**:
  - Kolkata Medical College
  - NRS Medical College

Objectives:

- **Clinical and Histopathological Evaluation**: Assess wound healing properties on surgical or traumatic wounds.
- **Clinical Parameters**: Measure **bleeding time (BT)**, **clotting time (CT)**, **wound volume**, and **macroscopic evaluation** of wound healing.
- **Histopathological Analysis**: Study tissue repair and scar formation.
- **Follow-up Study**: Assess **scar morphology** post-healing.

CLINICAL AND HISTOPATHOLOGICAL STUDY OF HT-11 TO EVALUATE ITS WOUND HEALING PROPERTIES

Key Findings:

- **Hemostatic and Pro-healing Effects**: HT-11 demonstrated **positive impact on coagulation** and **wound healing**.
- **Scar Formation**: **Positive role in reducing scar formation** was noted.
- **Safety**: No significant toxicity was observed.
- **Cosmetic Value**: Potential for improving the **cosmetic appearance** of healed wounds.

Conclusions:

- HT-11 **accelerated wound healing** and was **effective** as a **coagulant** in clinical settings.
- The study confirmed its **aseptic and pro-healing potential**.
- **Long-Term Observation Needed**: Further studies on **scar morphology** and **cosmetic value** are crucial.
- The **definite dearth** of compounds with both **aseptic and healing properties** highlighted the importance of HT-11 in future clinical applications.

WHY THIS MATTERS NOW?

Hemostasis-related complications contribute significantly to trauma deaths and surgical risks — delayed clotting can mean the difference between life and death.

Globally, over 1.9 million deaths per year are linked to uncontrolled bleeding and hemorrhage, yet safe, targeted, localized clotting solutions are rare.

Overuse of antibiotics and systemic hemostats has led to rising resistance, side effects, and ineffective wound management, especially in resource-limited settings.

There is **an urgent need for non-invasive, rapid-action, and localized clotting agents** that are safe, effective, and require no refrigeration or complicated administration.

HT 11 addresses this **critical healthcare gap with a robust, stable, and energy-driven plant-based solution** grounded in Indian Vedic knowledge systems.

Rooted in the **Vedic principle of Energy–Element Activation**, HT 11 does not suppress but **restores harmony** to the body's clotting mechanisms—**an approach missing in modern hemostats.**

This is a **Made-in-India innovation** built on our **own scientific heritage**, poised to offer scalable healthcare benefits both nationally and globally.

With **India's leadership in traditional medicine now globally recognized**, this is the moment to invest in solutions like HT 11 that blend **ancestral wisdom with modern biomedicine**.

VISION FOR THE FUTURE

- **To establish HT 11 as a global benchmark** for safe, effective, and indigenous hemostatic solutions across emergency care, trauma, surgery, and field settings.
- **To expand the Energy–Element Activation (EEA) platform** as a new category in bioregulation medicine—bridging Indian Vedic science with modern therapeutics.
- **To integrate Veda-based innovation into mainstream healthcare**, making India a leader in non-invasive, plant-powered, system-supportive medical interventions.
- **To democratize access** to affordable, easy-to-use, field-deployable emergency kits with HT 11 at the core—saving lives in rural, remote, and disaster-prone areas.
- **To inspire global policy and investment** in indigenous, eco-sustainable, and scientifically validated traditional knowledge systems.

THUS, WHAT IS HT-11 OFFERING?

Stop	Stop bleeding quickly and safely in trauma, accident, surgical, and battlefield settings—without systemic side effects. Also, excellent promise towards scar healing properties.
Reduce	Reduce dependency on synthetic clotting agents that carry risks of thrombosis, allergic reactions, or high cost.
Offer	Offer a potent, plant-based alternative for first responders, paramedics, and even laypeople—applicable as a spray, gel, or patch.
Enable	Enable effective clotting even in challenging scenarios, such as patients with coagulation disorders or on blood thinners.
Revolutionize	Revolutionize emergency care in India and beyond, especially in rural, low-resource, or disaster-struck zones.
Showcase	Showcase the power of Indian Vedic science in creating high-impact healthcare innovations rooted in native knowledge systems.

OBJECTIVE

To establish **HT 11** as a **safe, effective, and indigenous topical solution** for enhancing localized haemostasis, by completing preclinical validation and a pilot human clinical study within 18 months—thereby laying the foundation for **regulatory approval, scaled production, and eventual market launch**.

Rooted in the **Energy–Element Activation (EEA) Principle drawn from Indian Vedic knowledge**, this initiative aims to create a **science-backed, non-invasive, cost-effective, plant-based therapy** to address a critical unmet medical need in trauma care and bleeding control.

THE CASE FOR ACTION

HT-11 has already shown **promising results** in early trials, indicating strong potential as a topical hemostatic agent.

Expert evaluations have consistently called for **larger sample sizes** and **expanded clinical trials** to validate its efficacy at scale.

The **need for safe, rapid-acting, affordable bleeding control solutions** remains significant—particularly in emergency and low-resource settings.

This project responds to both **scientific potential** and **market necessity**, creating a bridge between traditional wisdom and modern biomedical innovation.