

***RAKTAMRUT* IN HEMOPHILIA – THE WORLD’S FIRST NOVEL AND CLINICALLY EVIDENCE-BASED *AYURVEDIC* PROPRIETARY MEDICINE FOR SUPPORTIVE MANAGEMENT OF HEMOPHILIA.**

Background and Purpose of the Invention:

Hemophilia is a rare, X-linked inherited bleeding disorder characterized by a deficiency or absence of specific coagulation factors essential for normal blood clotting. Hemophilia A, accounting for approximately 80-85% of all cases, results from a deficiency of Factor VIII, while Hemophilia B is caused by a deficiency of Factor IX.

This genetic defect leads to impaired clot formation, predisposing affected individuals to recurrent, prolonged, and often spontaneous bleeding episodes. These bleeding events predominantly occur into joints (hemarthrosis), leading to chronic pain, progressive arthropathy, and significant physical disability. Bleeds can also occur in muscles, soft tissues, and, critically, in the brain (intracranial hemorrhage), which can be life-threatening. The chronic nature of the disease, coupled with the risk of severe complications, profoundly impacts the physical, psychological, and socioeconomic well-being of patients and their families.

The cornerstone of modern Hemophilia management is replacement therapy with purified Factor VIII or Factor IX concentrates. Prophylactic administration of these factors, aimed at preventing bleeding episodes, has significantly improved patient outcomes, extending life expectancy and reducing joint damage, particularly in developed nations. However, this conventional treatment faces substantial challenges, especially in resource-constrained countries like India. The exorbitant cost of factor concentrates poses a formidable economic burden on patients and the healthcare system, rendering lifelong prophylaxis largely inaccessible for many. Furthermore, the need for frequent intravenous infusions contributes to a considerable treatment burden, impacting patient adherence and overall quality of life. The development of inhibitors (alloantibodies against infused factors) in a significant proportion of patients further complicates management, making standard replacement therapy ineffective and necessitating more complex and costly bypass agents.

Despite advancements, patients often continue to experience breakthrough bleeds and cumulative joint damage, highlighting the persistent unmet need for complementary therapeutic strategies that can enhance treatment efficacy, reduce factor consumption, and improve long-term outcomes.

Ayurveda, the traditional Indian system of medicine, offers a unique holistic perspective on disease. While it does not feature a direct etiological equivalent to "Hemophilia" as understood by modern genetic science, the symptomatic presentation of recurrent and spontaneous bleeding aligns closely with the Ayurvedic concept of Raktapitta (bleeding disorders). Raktapitta is primarily described as a condition resulting from the vitiation of Pitta Dosha and Rakta Dhatu (blood tissue). Aggravated Pitta, characterized by its hot (Ushna), sharp (Tikshna), and liquid (Drava) qualities, imbalances the fundamental properties of Rakta Dhatu, leading to its abnormal liquefaction and consequent leakage from the blood channels (Raktavaha Srotas). Ayurvedic texts describe various forms of Raktapitta based on the site of bleeding (e.g., from nose, mouth, rectum, urinary tract), many of which conceptually overlap with bleeding manifestations seen in Hemophilia. Furthermore, Ayurveda acknowledges hereditary predispositions to certain diseases, categorized as Kulaja Vikara, which broadly correlates with the genetic inheritance seen in Hemophilia. The core principles of Ayurvedic management for Raktapitta involve pacifying aggravated Pitta, strengthening Rakta Dhatu, promoting hemostasis (Raktastambhana), and purifying the blood (Rakta Shodhana).

Given the significant challenges in managing Hemophilia with current conventional therapies, particularly the economic burden, the potential for inhibitor development, and residual morbidity, exploring effective complementary interventions is imperative. This study aims to bridge the gap between modern hematology and traditional Ayurvedic wisdom. Based on the documented properties of its constituents in Ayurvedic literature, Raktamrut Vati holds promise as an adjunct therapy to modulate bleeding tendencies, reduce factor consumption, improve the overall quality of blood (as per Ayurvedic principles), and enhance the quality of life in Hemophilia patients.

Details and Scientific Rationale of the Invention:

Hemophilia is rare disorder, till date, there was no permanent cure for haemophilia all over the world. Specifically in rural area patients suffer many difficulties to get the clotting factors. Although they come to city hospitals, many obstacles they have to face for getting clotting factors. Sometimes they also may not get the clotting factor due to its unavailability. And if delayed for the treatment due to severe bleeding, patients get permanent disability, or may leading to death.

Also patients are not economically stable to purchase the clotting factors specifically in rural areas. That's why there is need of simple, effective, preventive, cost

beneficial medicine to be developed. So I developed simple, effective and supportive treatment for management of hemophiliac patients with the help of Ayurveda in scientific manner.

The invention, Raktamrut Vati, is a novel Ayurvedic proprietary medicine formulated for the management of Hemophilia A and B. It is the first known Ayurvedic medicine in the world designed explicitly for Hemophilia.

From the Ayurvedic perspective, Hemophilia correlates with *Raktapitta* (bleeding disorders due to vitiated Pitta in Rakta), *Pandu*, *Vatarakta*, and *Raktavaha Srotodushti* (impairment of the blood-carrying channels). Disturbance in *Pitta dosha* and weakening of *Raktadhatu* (blood tissue) lead to uncontrolled bleeding and poor clot formation. The formulation is carefully designed to correct these pathological imbalances while rejuvenating *Raktadhatu* and supporting the organs responsible for blood formation — mainly the liver, spleen, and bone marrow.

Raktamrut Vati is a Ayurvedic herbo-mineral formulation intended to be used as an adjuvant therapy alongside standard treatment (Factor VIII/IX replacement therapy) in patients with Hemophilia A and B. The primary intended use is to enhance hemostasis, reduce the frequency and severity of spontaneous and trauma-induced bleeding episodes, improve joint health, and support overall *Raktavaha Srotas* function in these patients.

Based on its formulation comprising multiple *Raktastambhaka* (hemostatic), *Raktashodhaka* (blood purifying), and *Rasayana* (rejuvenative) ingredients such as Udumbar, Ashwatha, Nyagrodha, Rohitaka, and Swarna Bhasma, Raktamrut Vati is proposed to:

- Strengthen vascular integrity
- Support the natural clotting process
- Reduce dependence on exogenous clotting factor administration
- Minimize joint damage and improve mobility
- Improve quality of life and fatigue associated with chronic bleeding disorders.

This formulation is not a substitute for factor replacement therapy but is expected to reduce the frequency of its requirement over time.

Raktamrut Vati (Tablet):

Raktamrut Vati is an proprietary Ayurvedic polyherbal formulation designed to manage bleeding disorders (Raktagata Vyadhis) by balancing the underlying doshic imbalances, primarily focusing on Pitta and Rakta Dhatu. While Ayurveda does not have a direct term for "Hemophilia" as a genetic factor deficiency, its principles of managing "Raktapitta" (a condition of bleeding due to vitiated blood and Pitta) are highly relevant to the symptomatic control and overall well-being of individuals with Hemophilia.

Hemophilia, a lifelong genetic bleeding disorder, presents a formidable challenge to affected individuals and healthcare systems globally. Characterized by recurrent, often spontaneous, bleeding episodes into joints, muscles, and vital organs, it leads to chronic pain, progressive arthropathy, severe disability, and carries the risk of life-threatening hemorrhages. Despite significant advancements in medical science, the management of Hemophilia continues to face substantial limitations, particularly in developing nations like India.

While recombinant or plasma-derived clotting factor replacement therapy has revolutionized Hemophilia care, enabling prophylaxis and improving life expectancy, several critical challenges persist that **underscore the need for complementary therapeutic approaches:**

- **Exorbitant Cost and Accessibility:** Clotting factor concentrates are exceptionally expensive, placing an immense financial burden on patients, families, and national healthcare budgets. In India, this high cost significantly limits widespread access to optimal prophylactic treatment, compelling many patients to rely on less effective on-demand treatment, leading to preventable complications and poorer long-term outcomes.
- **Logistical Burden and Adherence:** Regular intravenous infusions, often multiple times a week for prophylaxis, represent a considerable logistical challenge and lifestyle burden. This can lead to issues with adherence, particularly in rural or underserved areas lacking adequate healthcare infrastructure and trained personnel.
- **Inhibitor Development:** A major complication, especially in severe Hemophilia A, is the development of neutralizing antibodies (inhibitors) against the infused factor. This renders standard replacement therapy ineffective, necessitating more complex, significantly costlier, and often less efficacious bypass therapies, which further exacerbate the financial and clinical challenges.
- **Residual Morbidity and Quality of Life:** Even with consistent prophylaxis, many patients experience breakthrough bleeding episodes, leading to cumulative joint damage (arthropathy), chronic pain, and restricted mobility. These persistent physical limitations, coupled with the psychological and social impacts of living with a chronic bleeding disorder, significantly diminish the overall quality of life for Hemophilia patients.

These multifaceted challenges highlight an urgent and unmet need for safe, effective, and accessible adjunctive therapies that can reduce the reliance on frequent and high-dose factor concentrates, minimize bleeding episodes, mitigate long-term complications, and ultimately enhance the overall well-being and quality of life for individuals with Hemophilia.

Ayurvedic Perspective on Bleeding Disorders (Raktagata Vyadhis) and Rationale for Raktamrut Vati :

Ayurveda, the traditional Indian system of medicine, approaches bleeding disorders under the umbrella of Raktagata Vyadhis, with Raktapitta being the most relevant clinical entity directly corresponding to spontaneous hemorrhages. Raktapitta is characterized by the vitiation of Pitta Dosha and Rakta Dhatu (blood tissue). According to Ayurvedic principles, the aggravated Pitta, with its Ushna (hot), Tikshna (sharp), and Drava (liquid) qualities, impacts the integrity of Rakta Dhatu and destabilizes the Raktavaha Srotas (blood channels), leading to blood leakage from various orifices or internally. While Ayurveda does not describe Hemophilia in terms of genetic factor deficiency, it provides a holistic understanding of the internal bodily environment conducive to bleeding, and it acknowledges hereditary predispositions through the concept of Kulaja Vikara.

Raktamrut Vati is an Ayurvedic polyherbal formulation whose ingredients are traditionally revered for their properties in managing Raktapitta and supporting blood health:

- **Hemostatic & Pitta-Pacifying Action:** The core ingredients, Udumbar (*Ficus glomerata*), Ashwatha (*Ficus religiosa*), and Nyagrodh (*Ficus benghalensis*) (part of the revered Panchavalka), are characterized by their strong Kashaya (astringent) taste and Shita (cooling) potency. This combination is paramount for Raktastambhana (hemostasis) and directly pacifies the aggravated Pitta dosha, thereby addressing the root cause of bleeding from an Ayurvedic perspective. Their properties are believed to strengthen vascular walls and promote natural coagulation.
- **Blood Purification and Quality Improvement:** The inclusion of Rohitak (*Tecoma undulata*) and Sariva (*Hemidesmus indicus*) in the Bhavana (wet trituration) process provides Rakta Shodhana (blood purifying) and cooling properties. This aims to improve the quality of the vitiated Rakta Dhatu, preventing further leakage and supporting its inherent integrity.
- **Rejuvenation, Strength, and Vitality:** Swarna Bhasma (calcined gold), though in minute quantity, is a potent Rasayana (rejuvenative) and Balya (strength-promoting) ingredient. Along with Cow Milk and Krushna Tulasi in the Bhavana process, it contributes to overall systemic strength, enhances tissue repair (crucial for joint health), boosts vitality (Ojas), and acts as a bio-enhancer (Yogavahi), thereby optimizing the therapeutic effects of the other ingredients and improving overall well-being.

Raktamrut Vati works through the following mechanisms:

1. Enhancement of Natural Coagulation

Strengthens the physiological clotting cascade by supporting the natural synthesis and activation of endogenous clotting factors.

2. Hepatoprotective and Splenoprotective Action

Improves liver and spleen function — vital for the production, storage, and regulation of clotting factors and platelets.

3. **Raktasthambhana (Hemostatic Effect)**

Promotes natural arrest of bleeding in minor and moderate hemorrhages, preventing excessive blood loss.

4. **Rasayana (Rejuvenative) Effect**

Enhances overall tissue strength, improves immunity, and reduces oxidative stress, thus preventing recurrent episodes of bleeding.

5. **Anti-inflammatory and Analgesic Action**

Alleviates joint pain and inflammation associated with recurrent hemarthrosis (joint bleeds).

6. **Vascular Strengthening**

Improves elasticity and resilience of blood vessels, reducing the risk of capillary rupture and micro bleeds.

7. **Hematopoietic Support**

Enhances blood regeneration and hemoglobin levels, reducing anemia caused by chronic bleeding.

In clinical observations, patients treated with Raktamrut Vati demonstrated :

- Reduction in frequency, duration and severity of bleeding episodes.
- Decrease in dependence on plasma-derived or recombinant clotting factors.
- Enhancement of physiological clotting capability.
- Improvement in hemoglobin levels and overall blood health.
- Improved wound healing and joint mobility
- Relief from pain, swelling, and joint deformities caused by recurrent bleeding.

- Marked improvement in physical endurance, immunity, and quality of life.
- Absence of adverse drug reactions or allergic responses.

Raktamrut Vati acts as a preventive, supportive, and restorative medicine that works in harmony with the body's natural healing systems, offering a safer and more sustainable alternative to lifelong factor therapy.

This invention signifies a global Ayurvedic milestone, bridging the gap between traditional medicine and modern hematology. Raktamrut Vati stands as a breakthrough herbal innovation offering a ray of hope for millions of Hemophilia patients worldwide, fulfilling the need for a natural, affordable, and sustainable long-term therapeutic option.

Primary Conclusion:

1. It can be conclude that Raktamrut were able to successfully reduce the frequency of bleeding episodes and intensity of pain in hemophilia patients.
2. To reduce bleeding, they required relatively smaller number / fewer factor replacement treatments compared to earlier, when they were not taking Raktamrut Vati.
3. Raktamrut Proved to be effective in the managing severe haemophilia patients as a supportive therapy and was able to contribute towards reduced clotting factor requirements in Hemophilia Patients.

Formula (General Description):

Raktamrut Vati is an Ayurvedic polyherbal formulation, specifically designed with ingredients traditionally revered for their efficacy in managing various bleeding conditions and supporting overall blood health. The formulation incorporates crude powders of Udumbar (*Ficus glomerata*) fruit and bark, Ashwatha (*Ficus religiosa*) bark, and Nyagrodh (*Ficus benghalensis*) bark – all belonging to the *Ficus* family (Panchavalkala). These ingredients are renowned in Ayurveda for their potent Kashaya (astringent) taste and Shita (cooling) potency, rendering them highly effective as Raktastambhana (hemostatic) and Pitta-pacifying agents.

Their astringent properties are believed to strengthen vascular integrity and aid in coagulation, while their cooling effects counteract the "heat" of aggravated Pitta. The formulation also contains Swarna Bhasma (calcined gold), a highly valued metallic preparation in Ayurveda, known for its Rasayana (rejuvenative), Balya (strength-promoting),

and Tridosha-shamaka (dosha-balancing) properties. Swarna Bhasma is believed to enhance vitality, improve tissue regeneration, and act as a bio-enhancer (Yogavahi), improving the efficacy of other ingredients. The main ingredients are processed through Bhavana (wet trituration) with decoctions/juices of Rohitak (*Tecoma undulata*) bark, Sariva (*Hemidesmus indicus*) root, Krushna Tulasi (*Ocimum tenuiflorum*) leaf, and Indian Cow Milk. Rohitak and Sariva are acclaimed for their Rakta Shodhana (blood-purifying) and Pitta-pacifying actions, directly addressing the vitiated blood and heat in Raktapitta. Tulasi, known for its anti-inflammatory and immunomodulatory effects, and Cow Milk, for its cooling and nourishing properties, further contribute to the holistic action of the formulation.

Formula Summary :

Raktamrut Vati is composed of standardized extracts of multiple Ayurvedic plants including *Ficus* species, Swarna Bhasma, and Bhavana Dravyas such as *Tecoma undulata*, *Hemidesmus indicus*, *Ocimum tenuiflorum*, and Indian cow milk. The proportions are standardized and prepared under GMP-certified conditions.

Preparation Summary :

The preparation follows traditional Ayurvedic Bhavana and Mardana techniques — involving collection, authentication, premixing, wet blending with herbal decoctions and juices, controlled drying, tablet compression, and final standardization.

Flow Chart :

Collection → Authentication → Premix → Bhavana (Wet Blending)
→ Drying → Tablet Compression → Standardization → Packaging

Novelty and Inventive Features:

1. **World's First Ayurvedic Proprietary Medicine for Hemophilia:** Raktamrut Vati is the first globally recognized Adjunct Ayurvedic proprietary formulation specifically targeting the pathophysiology of Hemophilia (A and B).
2. **Addresses a Rare Disorder:** Hemophilia's low prevalence necessitates innovative approaches to its management.
3. **Bridges Ayurveda and Modern Medicine :** Showcases the potential of Ayurvedic formulations as adjunctive therapies in complex genetic disorders. Integrates Ayurvedic Pathology with Modern Hematology.

4. **Integrative Interpretation** : This integrative correlation between modern hematological mechanisms and Ayurvedic pathophysiology establishes a novel scientific bridge in Hemophilia management. Raktamrut uniquely acts at both biomedical and Ayurvedic levels — by addressing clotting factor deficiency (biomedical) and Raktadhatu–Pitta–Vata imbalance (Ayurvedic) — to restore hemostatic balance (Rakta Stambhana), enhance Dhatu Pushti, and improve overall quality of life in Hemophilia patients.
5. **Ayurvedic-Scientific Integration**: Combines the ancient Ayurvedic understanding of blood disorders (*Raktapitta*, *Pandu*, *Vatarakta*) with modern hematological science to develop a clinically effective formulation.
6. **Adjunctive and Preventive Therapy**: Demonstrates ability to significantly reduce dependence on clotting factor concentrates while serving as a prophylactic medicine to prevent spontaneous bleeding.
7. **Hepatosplenic and Hemostatic Dual Action**: Strengthens liver and spleen to naturally support production of clotting factors, while promoting immediate hemostasis.
8. **Safe, Natural, and Non-toxic**: Composed entirely of herbal constituents; free from synthetic chemicals, steroids, or preservatives; and has shown no side effects in clinical use.
9. **Affordable and Accessible Solution**: Offers a low-cost, easily manufacturable alternative suitable for low-resource settings, rural hospitals, and charitable organizations.
10. **Improved Quality of Life**: Enhances vitality, reduces pain and inflammation, and enables patients to lead an active, confident, and independent life.
11. **Socio-Medical Impact**: Empowers economically disadvantaged patients to access effective treatment without financial strain, contributing to public health equity.

Invention details:

The present invention, Raktamrut Vati, is an Ayurvedic proprietary medicine developed for the management, prevention, and supportive therapy of Hemophilia (A and B). The invention provides a safe, natural, and effective therapeutic solution that acts by improving coagulation balance, enhancing liver and spleen function, promoting hematopoiesis, and strengthening blood vessels.

Alignment with National Missions

1. **Make in India:** Indigenous Ayurvedic innovation for a global health challenge.
2. **Startup India / Innovate India:** Integrative medical innovation aligned with national entrepreneurship.
3. **Ayushman Bharat:** Promoting accessible Ayurvedic therapy for rare disorders.
4. **Atmanirbhar Bharat:** Strengthening India's self-reliant healthcare ecosystem.
5. **Vocal for Local:** Transitioning Ayurvedic research from local roots to global recognition.
6. **One Earth, One Health (G20):** Integrating traditional wisdom with global wellness vision.
7. **Digital India :** Digitally empowered Ayurvedic Research contributing to Digital India.

Social & Global Impact Statement

Raktamrut Vati represents a breakthrough Ayurvedic innovation addressing a rare genetic blood disorder through integrative science. It provides affordable, evidence-based, and accessible healthcare for Hemophilia patients. This invention stands as India's proud contribution to global health — a realization of the vision "From Local to Global" and "One Earth, One Health."